STERILIZATION ASSEMBLY DEVELOPMENT LABORATORY

DEVELOPMENT OF PROCEDURES FOR ESTIMATING THE CMTM MICROBIAL BURDEN

Task 11
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JPL CONTRACT 951624 - PHASE II

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CHANGES

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FOREWORD

To establish requirements for a terminal sterilization treatment, the burden of microbiological contaminants on a totally assembled capsule must be estimated. In addition, a technology for verifying the effectiveness of a final sterilization process and for monitoring the sterility of a capsule after the terminal sterilization cycle had to be developed. In Task 11, an approach to the establishment of such requirements, related to the use of a prototype capsule (CMTM) undergoing assembly/disassembly in the microbiologically-controlled environment(s) provided by the SADL facility at JPL, was evolved and documented.

The accomplishment of this Task required the integration of microbiological, biochemical, operations analysis, and statistical capabilities. This multidisciplined effort largely involved evaluations and extrapolations of data derived from literature studies of spacecraft biological burdens, assay techniques, and assembly procedures; rather than from laboratory studies, which were limited in this Task.

The eight sub-tasks which were specified in the work statement for Phase II were presented as separate entities with one exeption; each of the sub-tasks had its own objective. Because sub-tasks d and e all involved the study of methods for estimating surface burden on the CMTM during various assembly/disassembly stages in the SADL facility, the results for these sub-tasks were incorporated into a single part of the report.

To avoid confusion, it should be noted that, for Task implementation, the lettering system used to identify the sub-tasks in the work statement for Phase II was slightly altered. In the following list, current sub-task letters (per this report) are listed with the appropriate sub-task titles. The list further identifies by number that part of the report that covers each sub-task.

a. The evaluation of microbial techniques for determining surface burden. (Part 1)

b. The estimation of the microbial load on the CMTM subsystem assemblies prior to TA and/or FA cycles. (Part 2)

c. The estimation of the microbial load and verification of sterility on CMTM subsystem assemblies after TA and/or FA cycles. (Part 3)

d. The estimation of the microbial load at any particular stage of assembly of the CMTM. (Part 4)

e. The estimation of the microbial load on the assembled CMTM prior to terminal sterilization. (Part 4)

f. The development of procedures necessary for verifying sterility of the assembled CMTM. (Part 5)

g. The development and evaluation of procedures necessary to monitor the sterilized CMTM to insure noncontamination. (Part 6)

h. The development and proposal of the microbiological organizational structure necessary to implement and operate the microbiological monitoring and assay of the CMTM assembly. (Part 7)

ACKNOWLEDGMENT

This document is the result of the effort of a number of contributors. In general, each of the seven Parts that make up the document can be identified with one or more authors as follows:

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ABSTRACT

PART 1

EVALUATION OF TECHNIQUES FOR DETERMINING SURFACE BURDEN

An evaluation of swab, Rodac, lift-off, rinsing, and washing techniques as a means of determining surface burden was conducted. An analysis of the results indicated that the washing technique utilizing a surfactant reagent was the most efficient method for determining microbiological surface burdens under the given experimental conditions.

PART 2

ESTIMATION OF THE MICROBIAL LOAD ON THE CMTM SUBSYSTEM ASSEMBLIES PRIOR TO T.A. AND OR F.A. CYCLES

A detailed approach is presented for estimating the microbial burden on the various CMTM subsystem assemblies. References are cited in substantiation of applied estimation techniques. The total number of microbes on the entire CMTM before T.A./F.A. is estimated to be 4.4×10^6. Suggestions are made for improving sterilization procedures and for improving assay techniques.

PART 3

ESTIMATION OF MICROBIAL LOAD AND VERIFICATION OF STERILITY ON CMTM SUBASSEMBLIES AFTER T.A. AND/OR F.A. CYCLES

The probabilities of sterility for the various CMTM subassemblies following FA and/or TA Sterilization cycles are presented.

The impact limiter and the parachute in its container cannot be sterilized by the F.A. cycle or the T.A. cycles. These subassemblies will require an additional sterilization (pre-sterilization) operation. All other subassemblies are sterilized to a high degree of probability by both the F.A. and the T.A. cycles.

PART 4

ESTIMATION OF MICROBIAL LOAD AT ANY STAGE OF CMTM ASSEMBLY, AND ON THE ASSEMBLED CMTM

This part presents the development of techniques, procedures, and plans providing for estimation of microbial load upon the CMTM at any particular stage of assembly, and prior to terminal sterilization. It includes the results of the several tasks leading up to and relating to the development of the burden estimation procedures. Statistical verification and an analysis plan also appear.

PART 5

DEVELOPMENT OF PROCEDURES NECESSARY FOR VERIFYING STERILITY OF THE ASSEMBLED CMTM

This part provides an approach for the sterility verification of the CMTM following the NASA Planetary Quarantine guide lines. The approach selected fundamentally consists of three phases. First, the determination of the biological burden as the CMTM is sealed in the sterilization canister; second, exposure of the CMTM to a dry heat sterilization cycle; and third, verification that all parts of the CMTM experienced the required temperature for the requisite period of time to guarantee the required probability of sterility. Each phase of this approach requires rigorous controls, documentation and Quality Assurance verification. To determine if the CMTM has experienced the heat required for the necessary period of time, the use of 39 thermocouples as well as a chemical indicator (Alkaline Phosphatase) is recommended.

PART 6

DEVELOPMENT AND EVALUATION OF PROCEDURES TO MONITOR THE STERILIZED CMTM

The task of identifying candidate techniques to guarantee the integrity of the sealed sterilization canister containing the sterilized CMTM was investigated.

The present candidate technique is to seal off the HEPA filter after attaining ambient temperature by placing a rubber cap over the HEPA filter housing to reduce the known leak rate of the canister. A sterile inert partial atmosphere may then be impressed in the internal canister. As long as a certain maximum inert partial atmosphere above atmospheric pressure is maintained and monitored by inlet and outlet gauges, the sterility of the CMTM is guaranteed.

PART 7

PROPOSED MICROBIOLOGICAL ORGANIZATION FOR CMTM ASSEMBLY OPERATIONS

An organizational structure for the CMTM Assembly Operations has been developed where prime responsibility for on time performance, according to an Assembly Operations Plan, is vested in the Assembly Operations Manager supported by the Facilities, Microbiological and Quality Assurance Groups. The detailed relationships between the Microbiology Group and the other Groups are identified particularly for future CMTM Assembly effort.

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PART 4 (cont'd)

ILLUSTRATIONS

TABLES

ABBREVIATIONS

AFSCM	Air Force Systems Command Manual
$\overset{o}{A}$	Angstrom Unit = 10^{-10} Meters
Assem.	Assembly
AVSSD	AVCO Space Systems Division
Bio	Microbiological
CMTM	Capsule Mechanical Training Model
CRB	Contamination Review Board
D	Time to reduce a given microbial population 90% or one log in count
^{o}C	Degrees Centigrade
^{o}F	Degrees Fahrenheit
EASL	Experimental Assembly Sterilization Laboratory
EPD	Engineering Procedure Document
E.S.A.	Electronic Subsystem Assembly
ETO	Ethylene Oxide and Freon Mixture
F.A.	Flight Acceptance Test
HEPA	High Efficiency Particulate Air (Filter)
hrs.	Hours
JPL	Jet Propulsion Laboratory
kc/sec.	kilo-cycles/second
ml	milliliter
MRB	Material Review Board
NASA	National Aeronautics & Space Administration
Op., Oper.	Operation
oz.	Ounce
psi	Pounds/square inch
Q.A.	Quality Assurance
%R H	Relative Humidity
SADL	Sterilization Assembly Development Laboratory
T.A.	Type Approval Test
TSA	Trypticase Soy Agar

-NOTE-

This report contains information prepared by AVCO Corporation, Space Systems Division, under JPL subcontract. Its content is not necessarily endorsed by the Jet Propulsion Laboratory, California Institute of Technology, or the National Aeronautics and Space Administration

PART 1

THE EVALUATION OF MICROBIOLOGICAL TECHNIQUES

FOR DETERMINING SURFACE BURDEN

I INTRODUCTION.

A survey of surface sampling techniques, other than coupons, was performed. The initial effort was largely a literature search designed to reveal the most appropriate methods for sampling the surface on the CMTM.

The following techniques, plus various modifications and variations, were noted and considered.

1. Contact agar plate[2, 12, 15, 18, 19]
2. Agar sausage (contact)[4]
3. Millipore filter[10, 14, 20]
4. Lift-off tape
5. Spray gun (spray, rinse, collect)[6]
6. Vacuum probe[7]
7. Rinse[16, 17, 18]
8. Direct Surface Agar Plate[18, 20]
9. Swab[2, 3, 8, 18, 20]
10. Wash (rinse with surface active agent)
11. Syringe (contact agar)[10, 20]
12. Liquid agar rinse-off[20]
13. Agar Mold[5]
14. Agar-gauze (contact)[9]
15. Replicating floc[11]

From the above list, likely candidates were chosen for laboratory comparisons with the coupon method of sampling. The following

NOTE: Superscript refer to Bibliography - Appendix 1

criteria were employed in selecting five candidate methods:

1. Applicability to CMTM hardware
2. Amount of preparation and time required to perform each method
3. Need for modifications to present facilities or equipment

The five candidate methods selected for evaluation follow:

1. Contact Plate (Rodac)
2. Washing
3. Rinsing
4. Swabbing
5. Lift-off Tapes

II. EXPERIMENTAL PLANS.

Surfaces of aluminum alloy, stainless steel, and plastic were seeded with Bacillus globigii spores of different population densities and then assayed using the previously mentioned techniques.

A comparison was made of the efficiency of the different techniques. The bio-assay coupon procedure utilizing sonication was used as a standard.

III. METHODS AND MATERIALS.

A. Materials.

1. Spore suspension.

Bacillus globigii spores were grown and harvested as described in "Determination of the Heat Resistance of Microbial Isolate From the EASL"[1]. All dilutions for the purpose of

inoculation were made in 1% peptone water. Plate counts were made to determine the exact viable population. The population levels remained quite constant during the entire study period. The same stock solutions were used throughout the duration of the experiments.

2. Materials used as inoculated surfaces.

   a. Stainless steel, 2" x 2"

   b. Aluminum alloy, 2" x 2"

   c. Plexiglas, 2" x 2"

   All surfaces were treated as to insure their cleanliness then decontaminated with ETO 8 psi, 6 hrs., 130°F, 45% R.H.).

3. Biological materials.

   a. Trypticase Soy Agar (TSA)

   b. 1% Peptone Water

   c. Tween - 80

B. Methods.

1. The desired inoculum levels of Bacillus globigii spores (10^2, 10^3, 10^5, 10^7) were deposited onto the various surfaces with glass micro-pipettes. Prior to seeding, each surface was placed in a sterile plastic petri dish.

Following inoculation with the B. globigii spores, the surfaces were dried overnight at room temperature.

2. Rodac Procedure

   a. The rodac assay procedure was conducted in accordance with the NASA Standard Procedures for the Microbiological Assay of Space Hardware[2].

3. Swab Procedure

   a. The swab assay procedure deviated from the NASA Standard Procedures for the Microbiological Assay of Space Hardware only in that the swab head was placed in 50 mls of 1% peptone-water after swabbing and sonicated at 25 kc/sec. for 3.5 minutes.

4. Bio-assay Coupon Procedure

   a. The inoculated bio-assay coupons (stainless steel, aluminum alloy, and plexiglas) were placed in a 16 oz. bottle containing 50 mls 1% peptone "inoculum side down" and sonicated at 25 kc/sec. for 12 minutes.

   b. Serial dilutions of the sonicated liquid (where necessary) were made and plate counts were performed to determine the number of viable organisms removed by the bio-assay coupon technique.

5. Wash and Rinse Procedure

a. A sterile glass chromatography sprayer (Fisher/50 ml capacity) was used for both washing and rinsing methods. The sprayer, containing 20 mls of 0.5% sterile peptone-water, was connected to sterile latex tubing. Inserted in the tubing distal to the sprayer was a glass column packed with glass wool to filter out air contaminants. The spray was generated via attachment of the tubing to a compressed air line. The effluent generated onto the test surface was maintained at a distance (approximately one inch) such that the test surfaces were directly exposed to the wash or rinse effluent.

b. The inoculated test surfaces were held in a horizontal position (in sterile glass petri dishes): the lid of the petri dish was then elevated (approximately 45°) and the samples sprayed.

c. The washing method differed from the rinsing method only by the incorporation of 0.1% TWEEN-80 into the 20 mls of 0.5% peptone-water. The rinsing method did not utilize any detergent or surfactant in the peptone-water.

d. A 10 ml aliquot of the peptone wash (or rinse) fluid was removed and placed in sterile 8 oz. specimen jars. The peptone wash (or rinse) fluid was then sonicated for 3.5 minutes at 25 kc/sec. in a Branson sonicator to break up any spore "clumps".

e. Upon completion of sonication, serial dilutions (where necessary) were performed and plate counts conducted to determine the number of viable organisms removed by spraying techniques. 1 ml aliquots of the wash (or rinse) solution were dispensed into sterile petri dishes, followed by the addition of 20 mls of molten TSA.

6. All plates were incubated aerobically for 48 hrs at 32°C.

IV. Results

The results of experiments conducted to evaluate various assay methods utilizing the experimental techniques described in this study are presented in Table 1-1. This data indicates that the washing method was the most efficient means for assaying surface microbial burden. The efficiency of the wash recovery method exceeded that of the bio-assay coupon method which for purposes of this study was used as the standard reference technique.

V. Discussion

Under the experimental conditions described in this study, the swabbing and Rodac techniques were found to be the least efficient method for removal of surface burden. On all surfaces assayed, the washing technique was slightly more efficient than the rinsing method for spore removal. Evidently the low concentration of TWEEN-80 used in the wash fluids acted as a wetting agent and resulted in an increased removal of spores. The surfactant did not have a noticable

TABLE 1-1

A Comparison of the Percent Recovery of

Bacillus globigii spores from Plexiglas,

Stainless Steel and Aluminum Surfaces

	Spore Concentration per ml.			
	10^2	10^3	10^5	10^7
	All figures in % Recovery			
Surface Type-Plexiglas				
Method: Swab	N.A.	0	1	45
Wash	N.A.	66	51	73
Rinse	N.A.	15	43	63
Rodac	38	4	TNTC	N.A.
Control (Bio-assay Coupon)	0	0	29	62
Surface Type-Stainless Steel	10^2	10^3	10^5	10^7
Method: Swab	N.A.	23	6	44
Wash	N.A.	69	56	94
Rinse	N.A.	52	22	96
Rodac	40	10	0.3	N.A.
Control (Bio-assay Coupon)	0	68	46	92
Surface Type-Aluminum	10^2	10^3	10^5	10^7
Method: Swab	N.A.	0	31	53
Wash	N.A.	30	71	104
Rinse	N.A.	11	64	92
Rodac	10	4	TNTC	N.A.
Control (Bio-Assay Coupon)	0	19	83	92

N.A. - Not Applicable
TNTC - To numerous to count.

bactericidal or bacteriostatic effect. Plates containing TWEEN-80 and TSA were seeded with B. globigii and after incubation did not reveal any growth inhibition when compared to control cultures. The wash method appears to be equal to or greater in removal efficiency than the bio-assay coupon technique.

In general, the higher concentrations of spores appear to yield a higher percent recovery on all three surfaces with each technique employed. The result may be attributed to several factors including;

1. Surface properties of the materials evaluated.
2. The varying inoculation concentrations.
    a. Difference in drying and resultant spore die-off rates.
    b. Different affinity of spores to surfaces at various concentration levels.

Previous studies have indicated that the materials used as inoculating surfaces are not bacteriostatic or bactericidal (3). It was assumed that the die-off rates on each surface type at each spore concentration level was constant for the drying period. Thus the two above factors are interrelated and have been considered constant on each surface type and at each spore concentration in this study.

In addition to the previously discussed assay procedures an adhesive paper* was evaluated. Preliminary results from this effort indicated that the "lift-off" paper utilized was minimally effective

* Dry-Stick Paper, Manuf. by Dennison Paper Co.

in assaying surface microbial burden. However, it is recommended that additional studies be performed to evaluate other types of gummed paper or tape.

VI. Conclusions

1. The wash and rinse procedure is more efficient in assaying surface microbial burden than swabbing or rodacing.
2. These methods can be used for assaying coupons; however they would need additional experimentation and procedural development before they could be utilized on spacecraft hardware.

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APPENDIX 1-1

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PART 2

ESTIMATION OF THE MICROBIAL LOAD ON THE CMTM SUBASSEMBLIES PRIOR TO T.A. AND F.A. CYCLES

I. INTRODUCTION.

This report deals with the microbial loads on the Capsule Mechanical Training Model (CMTM) before the various flight acceptance (F.A.) and type approval (T.A.) tests.

The microbial burden on a subsystem assembly is influenced primarily by:

(1) The chemical composition of its component parts.

(2) The conditions of manufacture.

(3) The amount of exposure to microbial fallout after manufacture.

(4) The degree and type of handling after manufacture.

(5) Types of organisms present.

(6) Length of storage.

(7) The conditions of storage.

(8) Electrostatic factors.

All the above elements were considered in arriving at the various estimates in this report. In the absence of a detailed history on a particular item, engineering judgment was employed in conjunction with the best information available to arrive at an estimate. Conservative (high) figures were then used. Where deemed appropriate, authorities are cited.

The subsystem assemblies were assigned an arbitrary age of three months at the time of FA/TA; and were considered to have spent the last two months under protective covering. This baseline was considered necessary in order to circumvent the multitude of unknowns to which the units have been exposed while in the high bay area of Building 233.

Portner[1] and others[2] have shown that, in a non-clean room area, the viable particle count tends to reach a plateau of about 42 organisms per square inch after a few weeks. However, in this report, a higher value of 70 organisms per square inch will be used to estimate ordinary microbial fallout under conventional spacecraft assembly conditions. It has also been shown that, in the absence of continuing contamination, there is a rapid decline of vegetative organisms (about 4 logs in 14 days).[3][4] The die-off rate for bacterial spores is slower but substantial (about 50% reduction in 50 days). The "plateau phenomenon" and estimated decay rates have been employed in arriving at the burden estimates. When die-off rates were estimated for ordinary fallout, the organisms (a mixture of vegetative and spore forms) were considered to decline 90% after two months. When there was good reason to believe that a microbial population was predominantly spores, a die-off rate of 50% for 50 days was employed.

Charged microbial particles are electrostatically attracted to many non-metal surfaces, (i.e. impact limiter, retro-rocket, etc.) especially during periods of low humidity.[5] A conservative multiplication factor of 5 was employed when estimating such surface counts.

II. MICROBIAL BURDENS.

A. Data Encoder Subsystem and Dummy Electronic Subsystems[7]

A data encoder, as shown in Figure 2-1 is represented in this report as a typical electronic subsystem assembly. This unit is composed of a chassis, containing 15 modules, comprising 15 circuit boards, electronic piece parts, and cabling with interconnections. The values assigned to the eight electronic subsystems were arrived at from exhaustive analysis

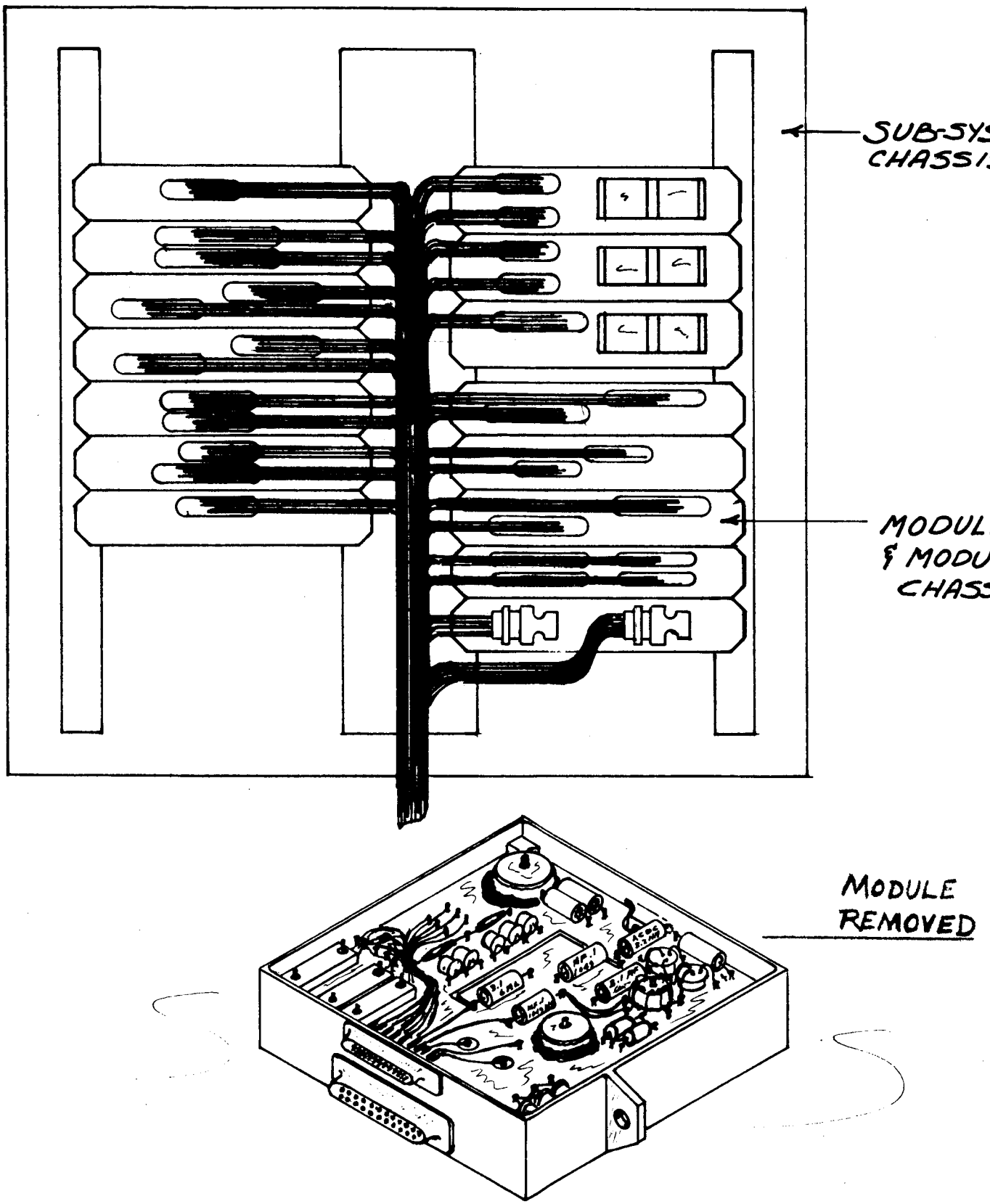

FIGURE 2-1 REPRESENTATIVE CHASSIS WITH MODULES (Data Encoder, RANGER-Block III)

of the data encoder. The various parameters that were considered as contributory factors to the increase or decrease of microbial burden on the data encoder subsystem are presented in Figure 2-2.

As a background for estimating the microbial burden of the electronic subsystem, it is necessary to consider the stages of its manufacture:

(1 The electronic piece parts are soldered onto circuit boards.

(2) The circuit board is conformal coated and mounted on the modules with the proper wiring and interconnections.

(3) The modules which have magnesium casings are mounted in the subsystem chassis.

The following list gives average numbers of electronic piece parts in each electronic subsystem assembly:

1.	Fastener connectors	5
2.	Capacitors	211
3.	Resistors	853
4.	Diodes	283
5.	Transistors	152
6.	Potentiometers	40
7.	Amplifiers	5
8.	Oscillators	5
9.	Electrical Lead Assemblies	2
10.	Electrical connectors	2
11.	Transformers	25
12.	Relay Latchings	66
13.	Chokes	8
	TOTAL ...	1657

Factors that Decrease Microbial Loads
(Letters positioned in flow chart)

a. Natural die-off

b. Cleaning of parts

c. Shake-off (bench check)

d. Parts screening

e. Alcohol wash

Factors that Increase Microbial Loads
(marks positioned in flow chart.)

* Manufacture Burden

** Fallout

*** Handling

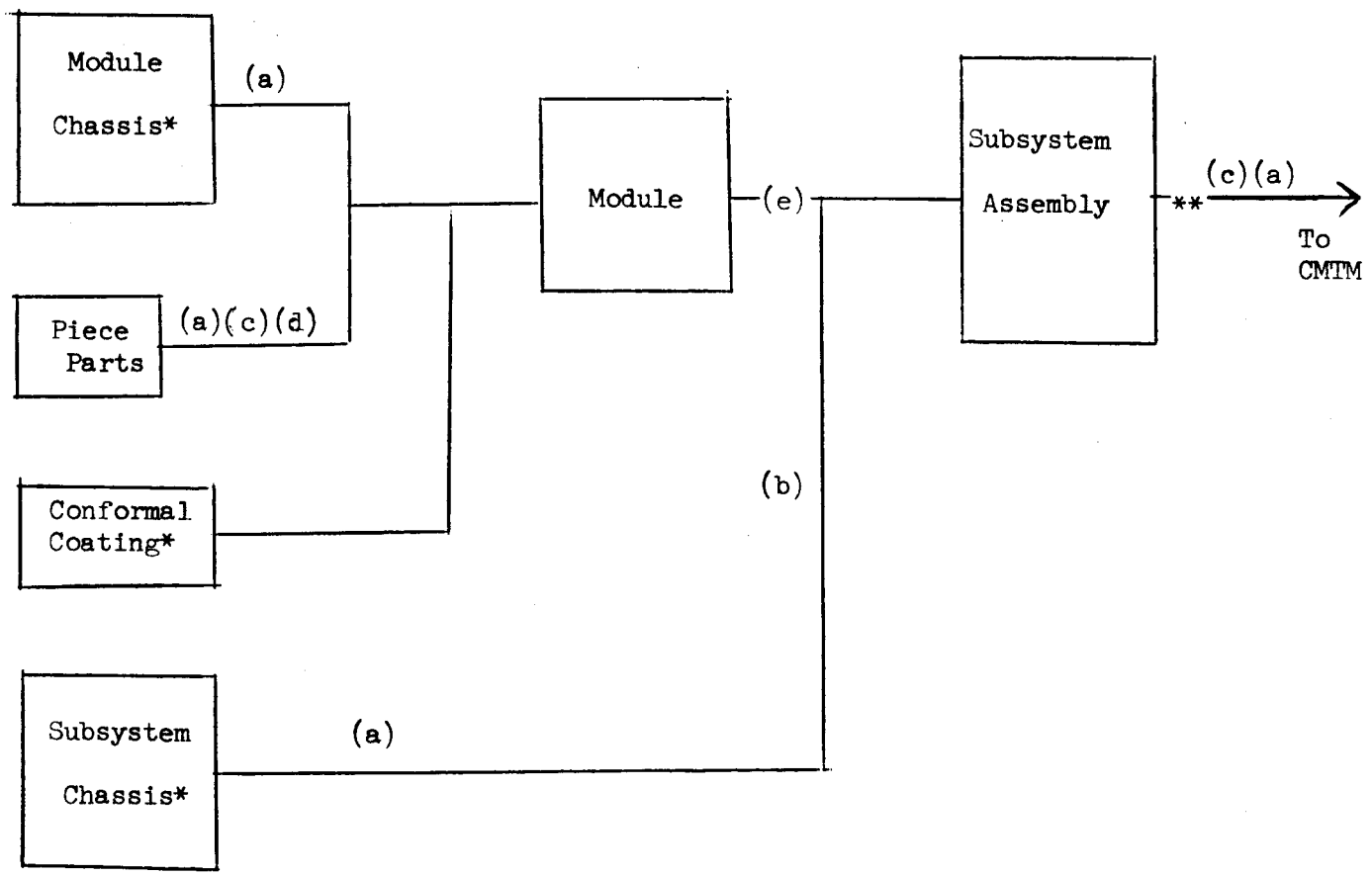

Figure 2-2 - Buildup of an Electronic Subsystem Assembly Illustrating Microbial Loading Considerations

a. Internal Burden Estimates

The circuit boards, electronic piece parts, conformal coating material, and wire coating were considered as possible sources of internal contamination.

The circuit boards were assigned a zero internal burden because of the high temperatures involved in their manufacure. (177°C for 30 minutes).

The wire coating material, teflon, also sees an extremely high temperature in its manufacture. It is applied to the wires at temperatures above 327°C. For this reason, the wire coating has been assigned a value of zero internal burden.

The parts screening techniques applied by JPL Quality Assurance generally utilize an elevated temperature cycle in excess of 125°C for 168 hours. This treatment destroys any internal burden. One of several possible exceptions to this treatment is the tantalum capacitor. However, in discussions with JPL parts engineers, it was indicated that, in any future application requiring sterilization of the system, the temperature screening would be increased to assure the availability of suitable parts. Therefore, we are considering the electronic piece parts as being internally sterile.

The conformal coating material (Castor oil-polyurethane) is not intrinsically germicidal, nor does is see sufficient heat (55°C) in its manufacture to ensure internal sterility. Bacteriostatic

substances are being developed, however, which will effectively block reproduction of bacteria in conformal material.* Twenty organisms per c.c. were assigned as the load for the conformal coating. There are about 20 c.c. of conformal coating per circuit board and 15 circuit boards. Thus, 20 x 20 x 15 = 6,000 organisms per electronic subsystem assembly before FA/TA.

b. Surface Burden Estimates.

Each of the eight aluminum subsystem chassis (aluminum face plate, support beams, side plates, etc. as shown in Figure 1)has a total exposed surface area of 1340 square inches and a total of 361 square inches of intimately joined** surfaces. The burden on all these surfaces before they receive their electronic modules can be assumed to be at least the "plateau" value of 42 per square inch. However, to be conservative, we will use a value of 70 per square inch. Therefore, the burden at this level is estimated to be 119,070 viable particles.

Shortly before the electronic modules are added, the subsystem chassis is washed down with M-50 compound (1,1,1, trichloroethane). This is assumed to decrease the microbial burden on the exposed surfaces from 93,800 to 9,380 organisms--primarily by mechanical removal. The 361 square inches of hidden surfaces would retain their original value of 25,270 viable particles. The new total on the subsystem chassis would be 34,650 viable particles.

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* NASA Case No. 10007 (Goddard Space Flight Center).

** Defined as surfaces so closely joined that additional bacterial fallout is excluded from both surfaces.

After the addition of the electronic modules, the total subsystem sees about a month of bench check. Several factors tend to resist microbial buildup on the subsystem chassis during this time. (1) The entire subsystem assembly is placed under cover when not being tested. (2) Many surfaces are occluded by the electronic modules. (3) Many surfaces are vertical and therefore receive less fallout.(6) (4) The burden between the intimately joined surfaces will continue to decay and could be expected to fall from 25,270 viable particles to about 16,000 microorganisms which will be principally spores. (5) Many of the fallout particles are dislodged whenever the unit is disturbed. (6) The microorganisms occluded by the installation of the electronic modules will continue to die off. This area, about 400 square inches, could be expected to show a burden drop from about 2800 (70 viable particles per square inch) to 1700 organisms

Because some of the fallout is dislodge by handling and shake-off, a net fallout of two viable particles per square inch of exposed area per day is assumed (8hr. day). Since all surfaces are not simultaneously exposed, the fallout is calculated on $\frac{1}{2}$ of the original exposed surfaces (1340 in.^{2}). This gives an estimate of 1340 viable particles per day (2 x 670), or 40,200 per month (40,200 x 30). The great majority of microbial burden added by handling is non-sporeforming in nature. Little, if any, of this burden is likely to survive until the FA/TA tests, two months hence. Thus, this burden will not be added to the total final microbial load.

The microbial surface burden on each of the subsystem chassis after bench check is given as:

40,000	Recent fallout
1,700	On areas occluded by modules
16,000	On intimately joined* surfaces
57,700	Viable particles

At this point, the subsystem assembly is wrapped and delivered to building 233. After two months under wraps, the fallout count could be expected to decrease at least 90% while the other burdens, which would be predominantly spores, should decrease at least 50%.

From the foregoing information the surface burden on each electronic module chassis at the time of TA/FA heat cycling is estimated at 12,850 organisms.

In calculating the microbial contamination on the electronic modules, all surfaces are considered together. The combined areas of the 15 modules with their circuit boards and electronic piece parts are about 2,160 square inches.

On the assumption that the completed modules had been stored free of direct fallout, a figure of 10 microbes per square inch is assigned as the burden load during storage, resulting in 21,600 microorganisms.

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* See page 2-9

During the build-up of the circuitry on the boards, the assemblers probably wear cotton gloves, cap, smock, and booties. Very little burden should be added due to handling. In fact, viable particles could easily be dislodged. However, to be on the conservative side, it will be assumed that the "plateau" level of 42 organisms per square inch is achieved giving a surface load of 142,212 organisms, including the electronic parts (with 1226 additional in.^{2})

As the construction of each electronic module is completed, it is rinsed with alcohol. This should reduce the burden by approximately two logs.(7) The resulting microbial surface count should be close to 1,400 for the electronic modules in the subassembly.

The number of viable particles which falls onto the modules while the modules are being mounted would probably be less than one per square inch of surface. However, a value of one viable particle per square inch will be assigned. Thus, a new total of 4,788 is obtained. Contamination from handling is not being calculated because of reasons previously given.

It is unlikely that a high overall surface count would be realized on the modules during the one month of bench testing--since only a small portion of the surfaces are directly

exposed. Additionally, most of the exposed surfaces are vertical. Taking an estimate of 70 viable particles per square inch of upward-facing areas, and $\frac{1}{2}$ of this (35) for the vertical surfaces, a new total of 11,300 is obtained.

After the prescribed two-month quarantine period, a pre-FA/TA viable particle count of about 1,130 should remain on the electronic modules.

c. Burden Totals

The complete microbial burden on each of the electronic chassis, before FA/TA, as estimated above, is:

1. Internal Burden (conformal) 6,000
2. Surface Burden
   (a) Aluminum Chassis 12,850
   (b) Electric modules 1,130
3. Total of 1. and 2. = 19,980 Organisms

The total for all eight electronic chassis would be about 160,000 viable particles.

Additionally, bay #8 electronic chassis has a large amount of wires and an "umbilical cord". Considering no internal burden in the wire coating, and assigning a value of 7 microbes per square inch (70, minus 90% die-off) one gets a count of 6,398 (about 914 square inches x 7) for the wires and cable in bay #8.

The total counts on all electronic chassis plus umbilical cord before FA/TA is estimated to be 1.2×10^5 organisms.

B. Impact Limiter

The impact limiter is a 45 inch sphere constructed from a hard grade of balsa wood. Irregular lengths of wood, 4" x 4", were bonded together with a resorcinol glue. These pieces created an internal surface area of 52,338 square inches; and an external surface area of 6,374 square inches. The outer surface is fiberglass coated.

a. Internal Burden

Plant interiors are normally sterile, therefore the only serious areas of concern are, (1) microbes added to the internal surfaces during manufacture, (2) the external surface burden, and, (3) the fiberglass coating.

Although resorcinol is weakly germicidal, we have no authority which would enable us to consider it sporicidal under these conditions. It very likely exerts a bacteriostatic action, however. It seems advisable to assign a value of 5 microbes per square inch of interior surface. This would give an internal burden count of 261,690 microbes.

The outer coat of fiberglass was cured at 135°C. for eight

hours. (5.7 D values). Therefore, the fiberglass is internally sterile--as is the adjacent balsa wood surface.

b. Surface Burden

The shape of the impact limiter offers very few horizontal surfaces onto which fallout may accumulate. On the other hand, it exerts an electrostatic attraction for particles suspended in the air. Therefore, where the estimated count would normally be seven microbes per square inch of total surface, only half of the sphere (3,187 sq. in.) is considered vulnerable at any one time. Seven times 3,187 x 5 (electrostatic factor) gives us 111,545 viable particles.

c. Total Burden

The microbial burden on and in the impact limiter before the FA/TA cycles is estimated to be 111,545 on the outer surface and 261,690 on the internal surfaces--for a total of 373,235 microorganisms.

C. Aeroshell

The aeroshell subsystem contains a large variety of surfaces:

(1) Sloping, exposed

(2) Sloping, sheltered

(3) Vertical, exposed

(4) Vertical, sheltered

(5) Horizontal, occluded

(6) Vertical occluded

(7) Closely joined

(8) Downward rims

The occluded areas (about 36,534 square inches) would very likely have a lower microbial burden than the other areas. Also, the sheltered areas would logically have a lower count than the outer areas. Also, the vertical outer surface should have a lower burden than the sloping surface. To reveal this difference, a load of 7 microbes per square inch is allotted to the exterior sloping surface; 5 to the outer cylinder; 4 to the lower rim; 3 to the sheltered areas; and 2 to the occluded areas:

Type of Surface	Surface (In.^{2})	Microbial Load/ In.^{2}	Pre-TA/FA Microbial Load Totals
Sloping, outer	25,345	7	177,415
Cylinder, outer	12,700	5	83,500
Joined and Occluded	36,534	2	73,068
Sheltered, open	46,210	3	138,630
Lower rim and inner cylinder	16,960	4	67,840
Totals	137,749		540,453

Table 2-1 - Estimated Loads on Various Aeroshell Surfaces.

D. Parachute Canister

The parachute canister is a cylindrical aluminum body containing a non-sterile nylon parachute. No history is available on the type of handling to which the parachute has been subjected. A burden of four organisms per square inch on the parachute surface seems to be the safest assumption.

Surface	$In.^2$	Microbe Per $In.^2$	Estimated Total Microorganisms at TA/FA
Top, outer	176	7	1232
Top, inner	155	4	620
Bottom, outer	240	7	1680
Bottom, inner	155	4	620
Top flange	21	7	147
Bottom flange	89	7	623
Side, outer	760	7	5320
Side, inner	720	4	2880
Parachute	690,768	4	2,763,072
Total			2,776,194 Organisms

Table 2-2 - Estimated Burden on Various Portions of the Parachute and Canister.

E. Relay Antenna

The relay antenna is a cylindrical aluminum body with a glass epoxy top.

The internal area of about 1,075 square inches is almost entirely occluded. This surface will be considered to have 4 organisms per square inch. The external surface will be assigned 7 viable particles per square inch. The amount and types of microbial burden on the relay antenna at TA/FA is estimated to be:

(1) Occluded burden . . . 4,300 organisms

(2) Surface burden . . . 7,609 organisms

Total 11,909 organisms

F. Rocket Motor

The rocket motor is constructed of fiberglass and resin. The nature of its manufacture (at about 300°C.) enables us to rule out internal burden.

The outer surface will be assigned a burden of 7 organisms plus the electrostatic factor of five--or 35 per square inch.

The inner surfaces will be assigned a value of 3 plus the electrostatic factor of 5--or 15 per $in.^2$.

Following is the amount and type of microbial burden on the rocket motor at time of FA/TA.

(1) Outer surface . . . 76,790

(2) Inner surface . . . 34,188

110,978 organisms

G. Payload Structure Assembly

This subsystem is constructed almost entirely of aluminum and contains about 1,500 square inches of intimately joined surfaces, and about 27,187 square inches of exposed surfaces.

By assigning a heavy manufacturing "plateau" of 70 microbes per square inch, we get a pre-FA/TA count of 7 microbes for each square inch on the payload structure assembly. This becomes:

(1) 10,500 viable particles per square inch of intimately joined surfaces.

(2) 190,309 viable particles per square inch of exposed surfaces.

200,809 Total microbial count before FA/TA.

H. Sterilization Canister

The sterilization canister has an inner surface area of 75,750 square inches. Considering half of this surface to be sheltered against fallout at any given time, an average count of 4 viable particles per square inch seems realistic. This gives 303,000 organisms on the inner surfaces of the sterilization canister before FA/TA. The outer surfaces were not calculated.

III. Totals

		INTERNAL BURDEN	SURFACE BURDEN	
			Intimately Joined ‡	External
1.	Electronic Payload Assembly			
	a. Total of 8 units	$4.8, \times 10^4$	6.4×10^4	4.7×10^4
	b. Umbilical cord	0	NEG.	6.4×10^3
2.	Impact Limiter	2.6×10^5	NEG.	1.1×10^5
3.	Aeroshell	0	7.3×10^4*	4.7×10^5
4.	Parachute and Canister	2.8×10^6	NEG.	9.0×10^3
5.	Relay Antenna	4.3×10^3*	NEG.	7.6×10^3
6.	Rocket Motor	0	NEG.	1.1×10^5
7.	Payload Structure Assembly	0	1.0×10^4	1.9×10^5
8.	Sterilization Canister	0	0	3.0×10^5
	Totals	3.1×10^6	1.5×10^5	1.2×10^6

Grand Total 4.4×10^6 organisms

Table 2-3- Estimated Microbial Load on the CMTM Before the FA/TA Cycles.

‡ See footnote, page 2-9
* Includes permanently occluded surfaces.
Neg. = Negligible

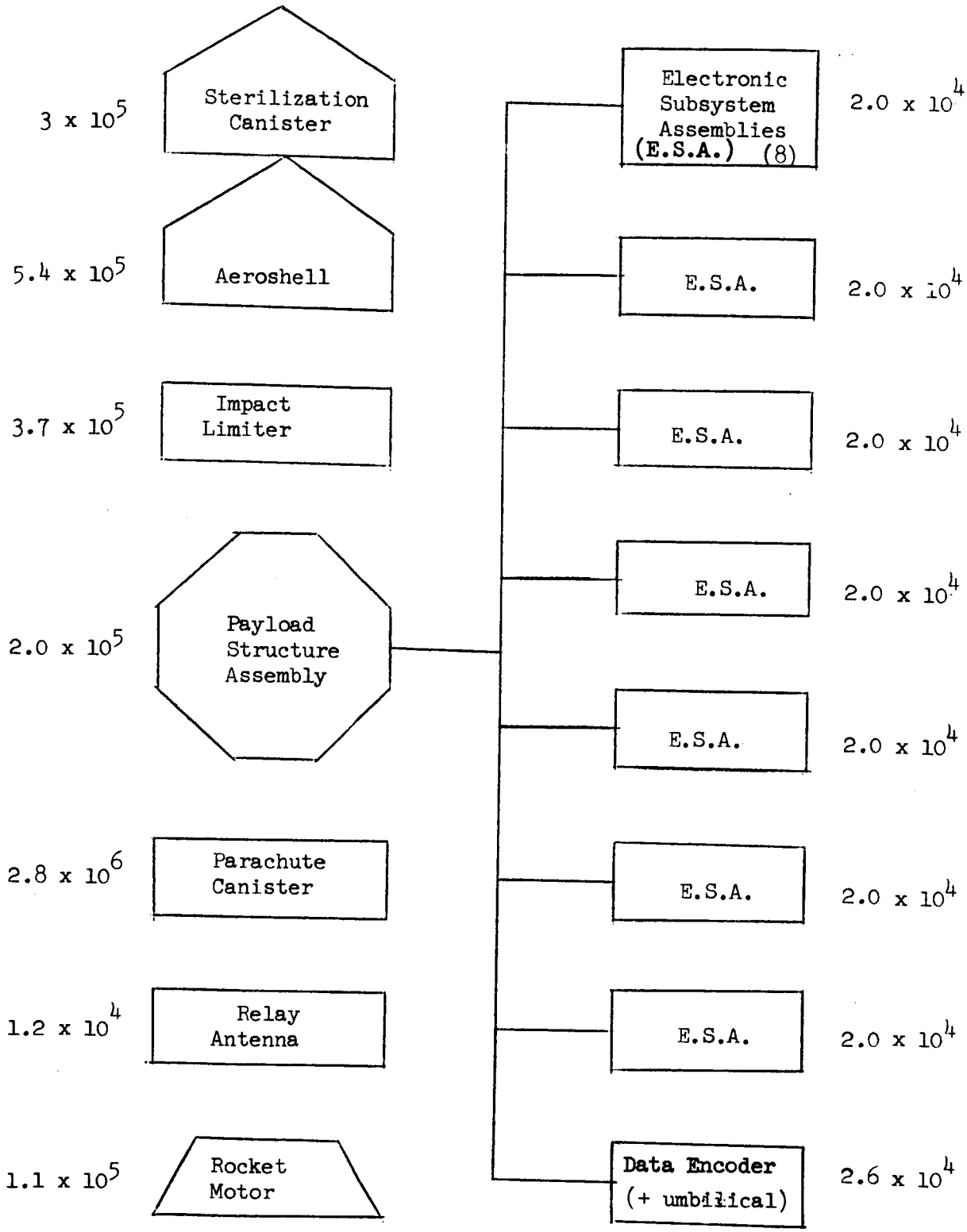

Figure 2-3
Estimated Microbial Distribution on the CMTM Prior to FA/TA.

IV. Discussion

As shown in Figure 2-3, a large portion of the microbial burden on the CMTM, before T.A./F.A., is found in the internal regions of the impact limiter and the parachute within the parachute canister. These units, and the other subsystem assemblies, will be subjected to ethylene oxide before being sent into the SADL assembly area. However, since ethylene oxide is a surface decontaminant, the parachute and impact limiter will carry their large internal loads until they are exposed to the terminal sterilization cycle.

The most questionable estimate in this report is felt to be the estimation of the internal burden of the conformal coating material. Under certain conditions, this material is said to support microbial populations It is unknown if these conditions existed for our material. It was assumed that no large scale reproduction of microbes occurred before, during, or after the application of the material to the circuit boards.

V. Recommendations

1. Sterilize the impact limiter and the parachute (within its containe prior to terminal sterilization cycle. This would enable the 8 CMI subassemblies to enter the SADL assembly area after ETO with an estimated microbial count of about 1.0×10^5. Without this precaution, the units would contain an estimated 3.2×10^6 microbes. About a 97% decrease would be realized.

By pre-sterilizing the impact limiter and parachute, the mathematical certainty of sterilization can be increased if the usual sterilization cycle is performed.

The effect of heat on the electronic components is of prime concern. If the sterilization heat cycle can be initiated before the centers of these two elements reach 125°C, the electronic components will probably see much less deleterious heat. From available information, it appears that the center of the balsa wood impact limiter would arrive at 125°C after 200 hours.

2. Investigate the possibilities of using the bacteriostatic conformal coating material reported in use by Goddard Space Flight Center.*

Ideally, of course, a bacteriocidal material would be preferred; however, if the manufacture of the suggested material can be performed under clean conditions, microbial loads can be more accurately estimated.

3. There are numerous spore-forming organisms, both aerobic and anaerobic, which have optimum growth temperatures below 30°C.(8) Investigation is this field could well demonstrate much higher fallout rates than those previously considered.

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* As described in NASA Case No. 10007 (Goddard Space Flight Center).

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PART 3

ESTIMATION OF MICROBIAL LOAD AND VERIFICATION OF STERILITY ON CMTM SUBASSEMBLIES AFTER T.A. AND/OR F.A. CYCLES

I Introduction

Task 11c requires an estimation of the microbial load and verification of sterility on the Capsule Mechanical Training Model (CMTM) subsystems after T.A. and/or F.A. cycles. The basic approach of the task was to apply the "D" values contained in the specified F.A./T.A. cycles to pre-F.A./T.A. biological burden estimates (as estimated in Part 2 of the report). By estimating initial biological burden and factoring in kill rates ("D" values for each F.A. and/or T.A. cycle), the probability of the subsystems being sterile was estimated.

It is recognized that those systems exposed to T.A. testing would not be used as future flight hardware, however, calculations were made to demonstrate the amount of biological lethality that T.A. articles are exposed to during T.A. heat sterilization.

For the purposes of this study, several assumptions have been made. These include:

1. The instantaneous heat-up and cool-down of all subsystems during T.A. and F.A. heat testing.
2. A D_{125} value of 3.5 hours and a D_{135} value of 1.4 hours used for the internal biological burden of all subsystems based upon a Z of 25°c. The D_{125} value used for surface microbial load was 0.5 hours.

3. All CMTM subsystems see F.A. heat and ETO testing.

II F.A./T.A. Tests and Their Applications

The type approval (T.A.) tests for ethylene oxide (ETO) and dry heat sterilization require six cycles with ETO and dry heat. The flight acceptance (F.A.) tests require only one cycle with ETO and one cycle with dry heat. The procedure for these tests are detailed in JPL Specification VOL-50503-ETS, "Environmental Specifications, Voyager Capsule Flight Equipment Type Approval and Flight Acceptance Test Procedures for the Heat Sterilization and Ethylene Oxide Decontamination Environments".

As previously stated, the applications of the "D" values for a F.A. or T.A. dry heat test to the estimated biological burden on a subsystem would yield the probability for sterility for that CMTM subsystem. This procedure was applied for determination of the internal, external and total biological (internal plus external) burdens on the CMTM subsystems.

Tables 3-1 & 3-2 describe the T.A./F.A. cycles for dry heat and ETO and the number of "D" values implied, based upon the assumptions previously given. Table 3-3 presents the level and distribution of the estimated microbial burden (internal, external and total) of the CMTM subsystems.

III Reduction in Microbial Load After T.A./F.A. Dry Heat Cycles.

Table 3-4 details the death rates ("D" values) obtained by exposing the CMTM Subsystem Assemblies to a F.A. dry heat cycle.

Table 3-1 ETO Cycles and "D" Values for T.A. and F.A. Testing

	T.A.	F.A.
1. No. of cycles	6	1
2. Time for each cycle	26 Hrs.	24 Hrs.
3. Temperature	50°c	40°c
4. Humidity	25-55%	35-55%
5. ETO Concentration	600 mg./liter	500 mg./liter
6. No. of "D" values	(?)*	(?)*

*No reliable figures are available. Unpredictable "skips" in ETO action have been experienced by many workers.

Table 3-2 Dry Heat Cycle and "D" Values for T.A. and F.A. Testing

(Based on a D_{125} = 3.5 hrs and a Z of 25° c.)

	T.A.	F.A.
1. No. of cycles	6	1
2. Time for each cycle	64 Hrs.	60 Hrs.
3. Temperature	135° c	125° c
4. No. of "D" values	276*	17

*Equal to 6 cycles, each cycle yielding 46 "D" values.

Table 3-3 Estimated Microbial Burden on the Subsystems of the CMTM Prior to T.A./F.A.

	Estimated* Internal Burden	Estimated* Surface Burden	Estimated* Total Burdens
1. Electronic Payload Assembly	1.1×10^5	4.7×10^4	1.6×10^5
2. Impact Limiter	2.6×10^5	1.1×10^5	3.7×10^5
3. Aeroshell	$7.3 \times 10^{4**}$	4.7×10^5	5.4×10^5
4. Parachute and Canister	2.8×10^6	9.0×10^3	2.8×10^6
5. Relay Antenna	$4.3 \times 10^{3**}$	7.6×10^3	1.2×10^4
6. Rocket Motor	0 ‡	1.1×10^5	1.1×10^5
7. Payload Structure Assembly	1.0×10^4	1.9×10^5	2.0×10^5
8. Sterilization Canister	0	3.0×10^5	3.0×10^5

*Values estimated in subtask 11b. (Part 2)

**Includes permanently occluded and intimately joined surface burdens.

‡No propellant present.

From Table 3-4, it can be seen that the CMTM subsystems will be internally sterile with a probability range of 4.3×10^{-14} for the relay antenna, to 2.8×10^{-5} for the internal load of the parachute and its canister.

The impact limiter (a balsa wood ball) is an extremely poor heat-transmitting structure, and, since the total volume of the impact limiter will not reach 125°C in the 76 hours total heating period, it will not be sterilized internally. The surface burden would be killed by the F.A. dry heat cycle. However, the internal sterility of the balsa wood impact limiter can be insured by applying a pre-terminal sterilization cycle to this item, as recommended in Part 2 of this document. If the parachute canister is also exposed to a pre-terminal sterilization cycle, then the CMTM subsystem having the highest probability of sterility after F.A. heat cycling would be the electronic payload assembly with a probability of 1.1×10^{-12}.

It has been previously mentioned that T.A. articles would probably not be used for flight hardware. However, to indicate the degree of microbial lethality encompassed by 6 T.A. heat cycles of 135°C for 64 hours dwell time, it can be seen in Table 3-2, those articles exposed to 6 T.A. heat cycles "see" approximately 276 "D's".

Thus the probability of obtaining sterility after exposing the CMTM subsystems to the T.A. dry heat cycles is extremely high. Using the "D" values and assumptions previously stated, the probability of sterility would range from 2.8×10^{-270} for the internal load of the Parachute

Table 3-4

Reduction of Microbial Burden on the CMTM Subassemblies Following F.A. Dry Heat Cycle. (125°C for 60 Hrs. = 17 "D"'s.) Total Heating Time of 76 Hrs.

	ESTIMATED PRE-F.A. BURDEN		ESTIMATED POST F.A. PROBABILITY OF STERILITY	
	Internal Burden	Surface Burden	Probability of Internal Sterility (D_{125} = 3.5 hours)	Probability of Surface Sterility (D_{125} = 30 minutes)
1. Electronic Payload Assembly	1.1×10^{5}	4.7×10^{4}	1.1×10^{-12}	4.7×10^{-116}
2. Impact Limiter	2.6×10^{5}	1.1×10^{5}	#	1.1×10^{-115}
3. Aeroshell	$7.3 \times 10^{*4}$	4.7×10^{5}	7.3×10^{-13}	4.7×10^{-115}
4. Parachute and Canister	2.8×10^{6}	9.0×10^{3}	$2.8 \times 10^{***-5}$	9.0×10^{-117}
5. Relay Antenna	$4.3 \times 10^{*3}$	7.6×10^{3}	4.3×10^{-14}	7.6×10^{-117}
6. Rocket Motor	0 †	1.1×10^{5}	N.A.	1.1×10^{-115}
7. Payload Structure Assembly	1.0×10^{4}	1.9×10^{5}	1.0×10^{-13}	1.9×10^{-115}
8. Sterilization Canister	0	3.0×10^{5}	N.A.	3.0×10^{-115}

= Estimated survivor count is 6.4 x 10 organisms. Based on information furnished by JPL.

* = Includes permanently occluded and intimately joined surface burdens.

** = Heat-up and cool-down values not estimated in kill.

*** = Estimated from data furnished by JPL. Estimated on the amount of 125° C heat at core.

N.A. = Not Applicable.

† = No propellant present.

and its Canister to 4.3×10^{-273} for the internal portion of the Relay Antenna.

Of the eight subsystems, it is probable that the electronic payload subsystem and rocket motor, in addition to the above mentioned subsystems, would "see" the dry heat testing. Structural articles such as the aeroshell, payload structure and sterilization canister will possibly not be exposed to T.A. cycling.

As in the case of the F.A. heat cycle, there is a problem with internal burden for the impact limiter. Even though 6 heat cycles at 135°C are applied for 64 hours each, the internal burden is still not completely destroyed. The center of the impact limiter will not "see" enough heat to guarantee complete kill For the T.A. dry heat test, it is required that after each heat-up cycle a cool-down period must follow; and, thus the heat can penetrate only a certain distance into the balsa wood ball during every heating cycle. The center of the balsa wood ball and adjacent areas would not be heated to a degree that would insure sterility.

IV Reduction in Microbial Load After T.A./F.A. Ethylene Oxide Cycles

Since the penetration of ETO into most materials is slight, the ETO F.A. cycle was considered to be effective only in decontaminating surfaces. In addition to this limitation, the chemical composition and cleanliness of the surface with the biological burden will influence the sterilizing effectiveness of the ETO. Moreover, due to a phenomenon known as "skips"*, the probability of surface sterility resulting from a single ethylene oxide F.A. cycle could not effectively be determined.

*Skips are a reduction or absence of kill capability obtained when ETO is used as a decontaminating agent. The exact cause and nature of the phenomenon is not clear. It is not feasible to try to predict a skip.

When an ethylene oxide T.A. test is performed, six cycles with a higher ETO concentration and longer time (see Table 3-1) than the F.A. test are required. Thus, a greater exposure to the ETO is obtained, but here again the question of "skips" in ETO activity arises.

The possibility of obtaining sterile surfaces for the CMTM subsystems during T.A./ETO testing is greater than that during F.A. cycles, but the probability of surface sterility still cannot be determined.

V Conclusions

The performance of the T.A. test cycles and for the F.A. sequence of test cycles would enhance the final probability of obtaining sterility for the CMTM subsystem. An exception must be made for the impact limiter and parachute and its container. These items will require a pre-sterilization cycle.

PART 4

ESTIMATION OF MICROBIAL LOAD AT ANY STAGE OF CMTM ASSEMBLY, AND ON THE ASSEMBLED CMTM

I Introduction

Task 11 requires the development of techniques for measuring and controlling the microbial load on the capsule mechanical training model (CMTM) at various stages of assembly in the controlled environment of the Sterilization Assembly Development Laboratory (SADL). Prior to admittance into the SADL, the subsystem assemblies of the CMTM undergo a Flight Acceptance (FA) test and an ethylene oxide treatment. The assembled CMTM, enclosed in its sterilization canister, undergoes a dry heat sterilization. This discussion is concerned with post FA and pre-terminal sterilization as well as the assembly stages.

Since no destructive testing is anticipated during this program, only surface burden can be estimated from analyses of measured data. Internal burden will have to be estimated by other means, e.g., through literature and judgment. The subject of internal burden is covered in the report on the estimation of pre-FA burden.* This report is, therefore, restricted to surface burden, i.e., the techniques for measuring and analyzing the data which can be accumulated during an assembly operation.

One of the requirements of Task 11 is the evaluation and comparison of various techniques for measuring surface burden. A study was being conducted simultaneous to the other required studies of the task, and the

Part 2

*In "The Estimation of the Microbial Load on the CMTM Subsystem Assemblies Prior to TA or FA Cycles" by R. L. Massey, the internal and occluded burden is estimated to be 3.2×10^6.

results are documented in another report. However, since the results were not to be available for the subject task, a given condition was that the best available method for measuring surface burden was by means of bio-assay coupons.

In addition to the subtasks mentioned above, Task 11 requires the development of means of guaranteeing sterilization during the terminal heat cycle, means of guaranteeing the integrity of the sterilization canister, and the development of a personnel organization. These subjects are also discussed in other Parts of this report.

Task 11 also implies other subtasks, the completions of which were necessary in order to carry out the specified requirements. These include the definitions of assembly operations, the breakdown of surfaces into zones, and the allocation of coupons. The implied as well as specified requirements are discussed in this report. The approaches used in satisfying these requirements are detailed in the sections which follow.

Sections IV, VII and VIII, concerning the statistical design and the statistical analysis plan were prepared by M.J. Massa, AVCO Corporation, Missile Systems Division. Sections II, III, V, and VI, concerning the assembly operations, zoning, and coupon allocation and removal schedules, and Appendices A through E were prepared by P.A. Kales, AVCO Corporation, Missile Systems Division. Section III was prepared with the assistance of R.L. Massey, and W.A. Brewer, AVCO Corporation, Space Systems Division. Appendix F was prepared by R.L. Massey and P.A. Kales. Appendix G was prepared by K. Bateman, AVCO Corporation, Space Systems Division.

II. Assembly Operations.

A. Definitions of Operations.

A primary step in accomplishing the task of burden estimation at various stages of assembly was, of course, to define the assembly operations so that estimation points could be determined. Using the assembly instructions[1] which were available, an operation plan was created after observing the vehicle being assembled. This plan defines operation steps by number, and indicates the numbers and types of hardware, tools and equipment, and personnel to be present for each operation.

The suggested assembly procedure appears in Appendix A. Areas of this plan may require revision as the program progresses. However, the necessity for such a plan in order to carry out the requirements of Task 11 justifies the procedure as it appears in Appendix A.

B. Points of Estimation.

An immediately essential task in defining a more complete statement of the problem was the establishment of estimation points relative to the assembly operations. Two sources of surface contamination were considered: fallout from the atmosphere and burden introduced by direct human contact.

Since a maximum of 500 samples (number of coupons to be assayed) are allowed per assembly, the number of estimation points permitted is

1 JPL Procedure CMTM 100.01

restricted. One estimation point will be when the assemblies enter the SADL for buildup; i.e., Section 1.0, Operation 5. Another will be when the CMTM is assembled but not yet inserted into the sterilization canister, i.e., Section 6.0, Operation 30. At least two other estimation points are desired to study fallout contamination, but the sample size restriction will not permit more than that. Since the amount of fallout contamination is a function of time, it is desired to have the other two estimation points at respectively one-third and two-thirds of the way through the buildup. These were determined to be Section 2.0, Operation 50 and Section 4.0, Operation 8

Surface areas which are contacted should be sampled as soon as possible after the assembly procedure calls for the contact to be made. These sample points were determined to be Section 1.0, Operation 90; Section 2.0, Operation 50; Section 3.0, Operation 90; Section 4.0, Operation 80; Section 5.0, Operation 60; Section 6.0, Operation 30 and Section 8.0, Operation 20. Another point of interest is Section 9.0, Operation 10, which is just before the canister cover is assembled to completely enclose the CMTM. Only the outside surface of the aeroshell assembly is exposed between Section 6.0, Operation 30 and Section 9.0, Operation 10.

Henceforth, the sample points will be referred to as Estimation Point 1 through 9, in accordance with the following definitions:

Estimation Point	Section	Operation Number
1	1.0	5
2	1.0	90
3	2.0	50
4	3.0	90
5	4.0	80
6	5.0	60
7	6.0	30
8	8.0	20
9	9.0	10

III Zoning

A. Classes

A study was conducted to determine which areas are contacted by assemblers during a buildup, and the results are documented in the Task 7* report (AVSSD-0303). It is assumed that the contacted areas will be the most heavily burdened, and for the purpose of coupon quantity determinations (Section IV) the assumption that the contacted areas have the highest variation of burden is used.

The analysis plan (Section VII) treats the problem as though burden can exist only at discrete levels. These classes of contamination levels were defined by means of biological and engineering judgments of bacteriologists familiar with the CMIM and the assembly procedures.

The following classes were defined.

A. Handled (contact) areas were assumed to have the heaviest burden level.

B. Areas subject to direct fallout in a laminar flow chamber were considered to have moderate burden.

C. Areas subject to indirect fallout in a laminar flow chamber were considered to have a light burden.

D. Uncontacted areas subject to no fallout were considered to have a very light burden.

In the analysis all surface areas classified within the same class (A, B, C, or D) will be considered to have the same level of burden.

B. Breakdown of Surfaces into Zones

Using the preceding definition, the surface areas of all the assem-

* "Assembly of the CMIM for purposes of determining areas of contact during the assembly process."

blies and the assembly operation procedures were reviewed in order to define and classify zones. Contact areas were classifed as Type A zones, non-contact areas facing horizontally upward as Type B, vertical and slanted non-contact surfaces as Type C, and non-contact areas facing downward as Type D.

During the buildup operations, some areas become occluded, mated, or otherwise inaccessible. With respect to these considerations, the zones were further subdivided. As a result, the seventy-five zones which are defined in Appendix B were established. The classifications of some zones change as the buildup progresses and areas become contacted, mated, occluded, or otherwise inaccessible. Appendix B classifies all seventy-five zones for each of the operations at which an estimate is to be made.

C. Computation of Surfaces Areas.

It was necessary to compile a list of all the surface zone areas in order to properly distribute the coupons (Section IV) and to analyze the data. This information was not available and had to be computed by the team working on Task 11. Many of the dimensions had to be measured directly from the hardware. Appendix B includes the computed areas.

The time restriction made it necessary to estimate many zone areas

without actually measuring dimensions. Appendix B indicates where such estimates were used.

IV. Distribution of Sample Points.

A. Conditions

The following conditions and definitions were established as a statistical basis for the coupon allocation plan:

1. The open CMTM surface areas at a given assembly stage in the SADL facility are defined to be identifiable areas which are exposed and accessible to the "coupon" method within the normal defined operations of the assembly process.

2. The various segments of the open CMTM surface areas at a given assembly stage can be consistently categorized into one of the following expected burden level zones: (a) heavy due to potential personal contact, (b) moderate, (c) light, or (d) very light.

3. Independent burden estimates are to be derived relative to: (a) total open CMTM surface areas at five defined assembly stages, and (b) potential personal contact open CMTM surface areas at four additional defined assembly stages.

4. The total number of coupons to be assayed in a given CMTM assembly in the SADL facility is defined to be 500.

The above conditions and definitions establish a statistical basis for a coupon allocation plan by specifying the populations to be sampled, i.e., the defined open CMTM surface areas at the nine defined assembly stages, and by defining the important factors for preparing a definitive coupon allocation plan, i.e., estimation points, total number of coupons to be assayed, etc.

B. Coupon Allocation Plan

The respective open CMTM surface area burden estimates to be derived would have measurable degrees of precision. The latter could be represented by expressing the statistical estimates in the form of confidence interval estimates, i.e., pairs of burden values which respectively bound the true burdens being estimated with a defined probability. In this form, the precision is reflected by the relative width of the intervals (the wider the width, the less precise the estimate).

There are several factors that influence the described precision of estimates. An obvious one is the sample size or number of coupons associated with a given estimate. Another factor is the inherent variability of the burden distribution relative to the open CMTM surface areas sampled (the greater the variability, the less precise the estimate). The essential objective of the coupon allocation plan was to apportion the 500 available coupons such that the precision of estimates would be maximized considering the several

influencing factors.

Critical to an efficient plan for achieving the above objective is the basic sampling selection procedure to be used. A common procedure is the one based on complete randomization. This procedure consists of selecting a given number of coupons at each of the nine defined assembly estimation points, each group of coupons (samples) being randomly representative of the defined surface area population. An alternative selection procedure is that based on stratified randomization. This procedure consists of subdividing (zoning) the respective surface area populations into subpopulations and selecting a given number of coupons (subsamples) from the respective subpopulations. It can be shown that at a given estimation point, if the identified subpopulations are different in expected burden levels, the stratified randomization procedure results in overall burden estimates of greater precision (Reference 1). Since the conditions and definitions given in IV A establish a basis for the stratified sampling procedure, the coupon allocation plan was based on this optimum sample selection method.

Consistent with the above and considering each of the nine estimates to be derived to be of equal importance, the objective of maximizing precision could be achieved by implementing the following apportionment formula: (References 1 and 2).

(1) $$n_i = \frac{a_i \cdot s_i}{\sum_{i=1}^{k} a_i \cdot s_i} \cdot (500)$$

where n_i = the number of coupons to be apportioned to the i^{th} subpopulation (surface areas of like zone at a given estimation point),

a_i = the area size of the i^{th} subpopulation,

s_i = the standard deviation (measure of burden variability) of the i^{th} subpopulation,

$\sum$ = mathematical symbol for "summed over,"

k = the number of identified subpopulations,

i = the identifying number of a given subpopulation, i.e., i= 1,2,3,...k.

A practical modification was made to the above formula due to the expected gross disparity in subpopulation apportionment. Thus, it was anticipated that some subpopulations could have more than 60 coupons allocated, whereas, other subpopulations could have less than 7 coupons allocated. Both conditions represent extremes from the statistical estimation point of view (small gain of information for additional samples over 60; large loss of information for samples less than 7). The modification therefore was to establish truncation points at 60 maximum, 7 minimum.

It is noted that the defined allocation formula requires known standard deviation (s_i) values. Estimates of these values are not available, and therefore comparable relative variability factor weights were constructed on the basis of biological judgment. Essentially, this consisted of scoring a relative variability factor of 1 to 8 to the various subpopulation zone categories. These factors to be symbolized as s_i^* would therefore represent preliminary estimates of the s_i values defining the minimum $s_i = 1$. Although justified for initial allocation, the resulting apportionment of the 500 coupons, utilizing these factors, should be considered preliminary and subject to revision as definitive assay data becomes available.

C. CMTM Information and Data

Table 41 presents the CMTM hardware and assembly process information and data pertinent to the implementation of the coupon allocation plan. The material in this table comes from Appendix B. Essentially it presents the following:

1. Column (1) identifies the various open CMTM surface area segments which at one assembly stage or another in the SADL facility are exposed and accessible to the coupon method of assay.

2. Column (2) gives the area dimensions of the respective open CMTM surface area segments identified in Column (1).

3. Columns (3) through (11) correspond to the nine CMTM assembly stage estimation points as defined in the Section II B. Columns (3), (5), (7), (9), and (11) are those associated with the total surface area estimates and Columns (4), (6), (8), and (10) are those associated with the potential personal contact surface area estimates. At the respective columns, the expected burden level categories (zones) into which the applicable surface area segments were classified are given in accordance with the following code:

A-1 Heavy burden zone, due to potential personal contact (initial contact).

A-2 Heavy burden zone, due to potential personal contact in the previous assembly stage.

A-3 Heavy burden zone, due to potential personal contact two assembly stages before.

A-N Heavy burden zone, due to potential personal contact N-1 assembly stages before.

B Moderate burden zone.

C Light burden zone

D Very light burden zone.

Table 4-2 presents the relative variability factors scored for the various expected burden level zones. Essentially based on biological judgment, the factors assigned reflect the reasonable condition of maximum variability in burden distribution for the A zones and

TABLE 4-1

OPEN CMTM SURFACE AREA AND ZONE DATA FOR COUPON ALLOCATION
(See Text)

Segment Code	Area (sq in)	ESTIMATION POINTS ▽ 1	2	3	4	5	6	7	8	9
A-1	25,345	D	C	C	C	C	C	C	C	C
A-2	12,700	D	C	C	C	C	C	C	C	C
A-3	406	D	D	D	A-1	A-2	A-3	A-4	-	-
A-4	406	D	D	D	A-1	A-2	A-3	A-4	-	-
A-5	406	D	D	D	A-1	A-2	A-3	A-4	-	-
A-6	406	D	D	D	A-1	A-2	A-3	A-4	-	-
A-7	4,084	D	D	D	-	-	-	-	-	-
A-8	373	D	D	D	-	-	-	-	-	-
A-9	287	D	D	D	-	-	-	-	-	-
A-10	20,000	D	D	D	D	D	D	D	-	-
A-11	16,960	D	D	D	C	C	C	C	-	-
A-12	1,378	D	D	D	D	D	D	D	-	-
A-13	1,464	D	D	D	D	D	D	D	-	-
A-16	190	D	D	D	C	C	C	C	-	-
B-1	810	D	D	D	A-1	A-2	A-3	A-4	-	-
B-2	462	D	D	D	-	-	-	-	-	-
B-3	68	D	D	D	A-1	A-2	A-3	A-4	-	-

TABLE 4-1 (Continued)

Segment Code	Area (sq in)	ESTIMATION POINTS →								
		1	2	3	4	5	6	7	8	9
C-1	150	D	D	D	D	D	D	D	A-1	-
C-2	40,000	-	-	-	-	-	-	-	D	D
C-4	2,800	-	-	-	-	-	-	-	D	D
C-5	1,400	-	-	-	-	-	-	-	C	C
D-1	392	D	A-1	A-2	A-3	A-4	A-5	A-6	-	-
D-2	2,180	D	C	C	C	C	C	C	-	-
D-3	320	D	-	-	-	-	-	-	-	-
D-4	30,340	D	-	-	-	-	-	-	-	-
D-6	56	D	A-1	A-2	A-3	A-4	A-5	A-6	-	-
D-7	310	D	C	C	C	C	C	C	-	-
D-8	46	D	-	-	-	-	-	-	-	-
D-9	4,791	D	-	-	-	-	-	-	-	-
I-1	622	D	B	B	-	-	-	-	-	-
I-2	1,308	D	D	A-1	-	-	-	-	-	-
I-3	1,282	D	C	C	-	-	-	-	-	-
I-4	2,565	D	D	-	-	-	-	-	-	-
I-5	622	D	D	-	-	-	-	-	-	-
M-1	306	D	C	C	C	C	-	-	-	-
M-2	1,253	D	D	D	D	D	D	D	-	-

TABLE 4-1 (Continued)

Segment Code	Area (sq in)	ESTIMATION POINTS →								
		1	2	3	4	5	6	7	8	9
M-3	1,574	D	D	D	D	D	D	D	-	-
M-4	500	D	D	D	D	D	B	B	-	-
M-5	25	D	D	D	D	D	B	B	-	-
O-1	56	D	D	D	D	D	-	-	-	-
O-2	54	D	D	D	D	D	-	-	-	-
P-1	176	D	B	B	B	-	-	-	-	-
P-2	240	D	D	D	D	A-1	-	-	-	-
P-3	760	D	C	C	C	B	-	-	-	-
P-4	21	D	B	B	B	-	-	-	-	-
P-5	89	D	D	D	D	-	-	-	-	-
R-1	19	D	B	B	B	B	B	B	-	-
R-2	254	D	D	D	D	D	D	A-1	-	-
R-3	550	D	D	D	D	D	D	A-1	-	-
R-4	264	D	D	D	D	D	D	-	-	-
S-1	366	D	-	-	-	-	-	-	-	-
S-2	7,022	D	C	C	C	C	C	C	-	-
S-3	264	D	D	D	D	D	D	-	-	-
S-4	1,236	D	D	D	D	D	D	D	-	-
S-5	1,635	D	D	D	D	D	D	D	-	-

TABLE 4-1 (Continued)

Segment Code	Area (sq in)	ESTIMATION POINTS [1] 1	2	3	4	5	6	7	8	9
S-6	12	D	A-1	A-2	A-3	-	-	-	-	-
S-7	128	D	A-1	A-2	A-3	A-4	-	-	-	-
S-8	5,798	D	-	-	-	-	-	-	-	-
S-9	14	D	D	D	D	D	-	-	-	-
S-10	7,180	D	-	-	-	-	-	-	-	-
S-11	922	D	B	B	-	-	-	-	-	-
S-12	2,610	D	C	-	-	-	-	-	-	-
U-1	255	D	D	D	D	D	D	D	A-1	-
U-2	116	D	B	B	B	B	B	B	A-1	-
U-3	795	D	B	B	B	B	B	B	B	-
U-4	20	D	-	-	-	-	-	-	-	-

[1] See Page 4 for estimation point definitions.

[2] This approximates the portion of the total C-5 area (2,800 sq in) which is accessible to coupon assay at estimation points 8 and 9.

TABLE 4-2

RELATIVE VARIABILITY FACTORS [1] (s_i^*) PRELIMINARY
BY OPEN CMTM SURFACE AREA BURDEN LEVEL CODES

(See Text)

ZONE	VARIABILITY FACTOR
A-1	8
A-2	7
A-3	6
A-4, A-5	5
A-6, A-7, etc.	4
B	4
C	2
D	1

[1] The factors are estimates of the relative variability of the burden distribution within open CMTM surface areas of like zones. These estimates were based on biological judgement pending definitive assay data.

the minimum variability in burden distribution in the very light D zones.

D. Coupon Allocation Plan Implementation and Results

Table 43 presents the calculation and results in the implementation of the coupon allocation plan. Columns (1), (2), and (3) identify the subpopulations of the open CMTM surface areas at the respective assembly stage estimation points. For example at Estimation Point #3, (defined in Appendix A as immediately before the aeroshell assembly), the total open CMTM surface areas are subdivided into five subpopulations. These five consist of the area segments classified into the A-1, A-2, B, C, and D burden level types. Similarly, the subpopulations are identified for the remaining assembly stage estimation points.

Columns (4) and (5) give respectively the area sizes (a_i) and variability factors (s_i^*) of the associated subpopulations. Columns (6), and (7) give the calculations for implementing the apportionment formula.

The final results of the coupon allocation plan are given in Column (8). These results reflect the application of the truncation points 60 maximum, 7 minimum. The latter resulted in 5 unassigned coupons. As noted, these were distributed over five subpopulations in which relatively low apportionment occurred.

TABLE 4-3

CMTM COUPON ALLOCATION PLAN IMPLEMENTATION AND RESULTS

SUB POP. NO. (i)	EST. PT.	ZONE	AREA (sq in) (a_i)	VAR. FACT (s_i^*)	$a_i s_i^*$	UNADJ. ALLOC. (m_i)	FINAL ALLOC.
1	1	D	165,243	1	165,243	93	60
2	2	A-1	588	8	4,704	3	7
3	3	A-1	1,308	8	10,464	6	7
4	3	A-2	588	7	4,116	2	7
5	3	B	2,671	4	10,684	6	7
6	3	C	49,905	2	99,810	56	56
7	3	D	56,113	1	56,113	31	31
8	4	A-1	2,502	8	20,016	11	12
9	4	A-3	588	6	3,528	2	7
10	5	A-1	240	8	1,920	1	7
11	5	A-2	2,502	7	17,514	10	11
12	5	A-4	576	5	2,880	2	7
13	5	B	1,690	4	6,760	4	7
14	5	C	65,013	2	130,026	73	60
15	5	D	30,926	1	30,926	17	17
16	6	A-3	2,502	6	15,012	8	9
17	6	A-5	448	5	2,240	1	7
18	7	A-1	804	8	6,432	4	7
19	7	A-4	2,502	5	12,510	7	8
20	7	A-6	448	4	1,792	1	7
21	7	B	1,455	4	5,820	3	7
22	7	C	64,707	2	129,414	73	60

TABLE 4-3 (Continued)

CMTM COUPON ALLOCATION PLAN IMPLEMENTATION AND RESULTS

SUB POP. NO. (i)	EST. PT.	ZONE	AREA (sq in) (a_i)	VAR. FACT (s_i^*)	$a_i s_i^*$	UNADJ. ALLOC. (m_i)	FIN ALL
23	7	D	28,945	1	28,945	16	17
24	8	A-1	521	8	4,168	2	7
25	9	C	39,445	2	78,890	44	44
26	9	D	42,800	1	42,800	24	24
				TOTAL.....	892,727	500	500

Ψ = An additional coupon was allocated for complete utilization of the 500 coupons.

E. References

(1) Statistical Methods Applied to Experiments in Agriculture and Biology, George W. Snedecor, Iowa State College Press, Ames, Iowa, Fifth Edition.

(2) Statistical Analysis in Chemistry and the Chemical Industry, C.A. Bennett and N.L. Franklin, John Wiley & Sons Inc., 1954.

V. Allocation of Coupons

A. Assay Points

Whereas Table 4-3 goes as far as assigning sample sizes (coupon quantities) to the zone classes for each of the nine estimation points, the task of allocating these quantities among the seventy-five zones still remained. The general policy was to distribute the quantity for each class (for a particular estimation point) among all the zones of that class according to the surface areas and configurations of the zones, i.e., configuration permitting, quantity was made proportional to area.

The results are shown in Appendix B, where the number of coupons to be removed for assay from each zone at each estimation point is listed.

B. Dummy Coupons

Three considerations led to desirability of attaching more coupons than are allocated in Table 4-3 and in Appendix B.

1. Personnel working on and around the CMTM can bias results because of their conscious or subconscious awareness of coupons. This bias can be reduced by attaching additional

coupons along with the ones to be assayed. These additional coupons will serve only as decoys and will be removed from all surfaces just prior to occlusion. They will not be assayed.

2. In case some coupons fall off during assembly, are damaged or for some other reason cannot be assayed, the availability of other coupons which can be substituted is desirable.

3. Additional coupons may be desired for special studies which may take place. One such study is the quarantine period described in Sections VI, B and C. Approximately twice as many dummy coupons as assay coupons were assigned to each zone. More dummy coupons were attached where the surface areas were too small. Appendix B indicates in parentheses the quantity of dummy coupons and the stage of assembly at which they are to be removed.

C. Coupon Identification

Appendix B calls for 1390 coupons, including the dummy coupons. A five character code will be used for identifying each coupon, and it will also identify the subsystem assembly and location. The first character will be a letter identifying the subsystem assembly or part to which the coupon is attached. The letter A will indicate that the coupon will be attached to part of the aeroshell, B to the band assembly clamp, C to the sterilization canister, D to part of the seven dummy chassis or live data encoder, I to the impact limiter, M to the deorbit motor, O to the motor clamp, P to the parachute canister, R to the relay link antenna, S to the payload structure, and U to the umbilical chord assembly.

B. Quarantine Considerations

During some buildups a quarantine period will be required after the CMTM is built. Its purpose will be to determine the effect upon microbial load of leaving the assembled CMTM in quarantine.

The basis of comparison will be the results obtained from the data of Estimation Point #7. Therefore, the same quantity of coupons should be removed for the post quarantine period as for Estimation Point #7 and they should correspond.

Appendix D lists the coupons to be removed for assay after the quarantine period. Each coupon listed in Appendix D corresponds to a coupon in the Estimation Point #7 schedule of Appendix C. The Appendix D schedule was prepared by selecting each coupon as close as possible to its corresponding coupon in the Estimation Point #7 schedule. Random Selection, therefore was not used.

When a quarantine period is to take place, there will be no dummy coupon removal at Estimation Point #7. The dummy coupons scheduled for removal during this operation will be removed after the quarantine period instead.

Recording of the date and time of coupon removals for assay will also be required after the quarantine. The coupons to be assayed should be removed before the dummy coupons are removed.

C. Modifications

In order to determine or verify the effectiveness of the costly SADL facility, data will be accumulated from a series of buildups outside

the SADL. Some of these buildups will take place in an open high bay area, while others will take place under a laminar flow tent.

These special assembly operations will not be preceded by a TA or FA test, and the CMTM will not be installed in the sterilization canister. To maintain a basis for comparison, the removal and assay schedules of Appendices C and D will apply, but slight modifications will be imposed by the different set of conditions.

There will be no coupons removed for assays scheduled for Estimation Point Numbers 1, 8 or 9. There will, of course, be no coupons attached to or removed from the sterilization canister.

D. Suggested Data Forms

Another Task 11 requirement was the design of forms for recording raw data pertaining to hardware, environment, and personnel assays. A set of suggested forms appear in Appendix F.

VII. Analysis Plan

A. Statistical Basis

Each of the nine definitive experiments can be represented as shown in Table 4-4 Thus, at a defined CMTM assembly stage, Table 4 represents the open CMTM surface area population as consisting of k ($k \geq 1$) subpopulations (zones). The number of coupons initially attached to the respective subpopulations are represented by n_i ($i = 1, 2, \ldots, k$).

structure, and U to the umbilical chord assembly.

The next two characters will be a two digit number to identify the zone. The final two digit number will identify the coupon number within the zone. As an example, coupon number A04-07 represents the seventh coupon of the fourth zone of the Aeroshell assembly, See Figure 4-1.

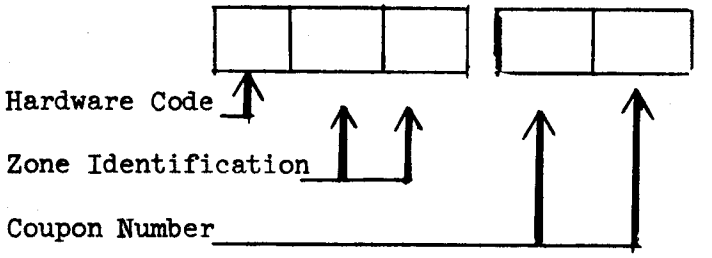

Figure 4-1. Identification of Coupons

Zones 1 and 2 of the Aeroshell are the only zones which have more than 100 coupon assignments. An X as the second character will be used to indicate a coupon number between 100 and 199, and a Y will indicate a coupon number between 200 and 299. As examples, the first coupon of zone 1 will be identified as A01-01, the one hundred and first as AX1-01, and the two hundred and first as AY1-01.

D. Coupon Locations

One of the accomplished tasks was the identification of coupon locations on the subsystem assembly surfaces. The locations for

1390 coupons were marked on the hardware surfaces. Coupon identification numbers are also marked on the hardware surfaces at proper locations.

Appendix G. contains subsystem assembly drawings which illustrate the coupon locations. The number of coupons in each zone can be taken from either Appendix B or Appendix E.

VI. Coupon Removal Schedule

A. Removal Sequence

The experiment design (Section IV) requires that a given quantity of random samples be taken from the different zones during specified operations in accordance with Appendix B. By means of random number sequences the schedules of Appendix C were created.

The schedules list the coupons to be removed for assay during each of the nine operations. The schedules of Appendix C also list the zones from which dummy coupons are to be removed during each operation. All coupons are to be removed from zones about to become occluded by the assembly operation to follow.

At each of the nine operations calling for coupon removal, the coupons which are to be assayed should be taken off the CMTM hardware first. They must remain identified, and the date and time of removal should be recorded. If a coupon designated for removal and assay is lost, accidentally falls off its surface, or for some other reason cannot be used for an assay, the nearest dummy coupon can be substituted. Appendix E identifies which are the dummy coupons.

Table 4-4
CMTM Surface Area Coupon Assay Experiment
General Representation
(SEE TEXT)

Subpop. No.	Initial Coupons No.	Unadj. Size	POPULATION				SAMPLE			
			Adj. Size	Burden Values	Average	Variance	Size	Burden Values	Average	Variance
1	n'_1	N'_1	N_1	$X_{11}, X_{12}, \ldots X_{1N_1}$	μ_1	σ_1^2	n_1	$x_{11}, x_{12}, \ldots x_{1n_1}$	$\bar{x}_1$	s_1^2
2	n'_2	N'_2	N_2	$X_{21}, X_{22}, \ldots X_{2N_2}$	μ_2	σ_2^2	n_2	$x_{21}, x_{22}, \ldots x_{2n_2}$	$\bar{x}_2$	s_2^2
'	'	'	'	' ' '	'	'	'	' ' '	'	'
'	'	'	'	' ' '	'	'	'	' ' '	'	'
'	'	'	'	' ' '	'	'	'	' ' '	'	'
'	'	'	'	' ' '	'	'	'	' ' '	'	'
'	'	'	'	' ' '	'	'	'	' ' '	'	'
'	'	'	'	' ' '	'	'	'	' ' '	'	'
k	n'_k	N'_k	N_k	$X_{k1}, X_{k2}, \ldots X_{kN_k}$	μ_k	σ_k^2	n_k	$x_{k1}, x_{k2}, \ldots x_{kn_k}$	$\bar{x}_k$	s_k^2

Each subpopulation is initially represented as consisting of N_i' surface area elements, each element defined to be of the coupon constant area size (A_c, sq. in.). Accordingly, the N_i' can be calculated as follows:

$$(1) \quad N_i' = \frac{A_i}{A_c}$$

where A_i = the area size of the i^{th} subpopulation (sq. in.).

The adjusted subpopulations for which the microbial burden estimates are to apply are represented as consisting of N_i elements. This adjustment is required since portions of the subpopulations become occluded areas upon initial attachment of the N_i' coupons. [1] Accordingly, the N_i can be calculated as follows:

$$(2) \quad N_i' = N_i' - n_i'$$

The true (although unknown) microbial burdens of the N_i surface

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[1] The number of coupons initially attached to the i^{th} subpopulation includes dummy coupons, coupons that may have been previously detached relative to the i^{th} subpopulation, etc. Essentially this condition precludes the CMTM surface areas covered by coupons from the defined subpopulations. This is justified since the coupon assay data would not be representative of the covered surface areas. Precluding the latter, the burden estimates in effect assumes that the initially covered areas have zero burden. Biological judgment therefore, would be required for either, (1) validating the assumption by the coupon sampling procedures used; or (2) adjusting the burden estimates where deemed necessary.

area elements are represented as X_{i1}, X_{i2}, . . . $X_{i\ N_i}$, with associated average and variance (measure of variability) paramters, μ_i and σ_i^2, respectively. The total microbial burden of the i^{th} subpopulation (B_i) can therefore be represented as follows:

$$(3)\quad B_i = X_{i1} + X_{i2} + \ldots\ldots + X_{i\ N_i} = N_i\,\mu_i$$

where the N_i = the number of surface area elements in the i^{th} subpopulation, μ_i = the average microbial burden per defined element.

The total microbial burden parameter (B_t) at the defined CMTM assembly stage can also be represented, as follows:

$$(4)\quad B_t = N_1\mu_1 + N_2\mu_2 \ldots\ldots + N_k\mu_k = \sum_{i=1}^{k} N_i\mu_i$$

where $\sum$ is a mathematical symbol for "summed over".

The random samples of the N_i surface area elements, as essentially simulated by the detached coupons, are represented by the n_i samples. The microbial burden values of the n_i assayed coupons are represented as x_{i1}, x_{i2}, ... $x_{i\ n_i}$. The objective of the experiment is to derive, on the basis of the latter assay data, best estimates and 90 percent confidence interval estimates of the respective B_i and B_t parameters as represented.

B. Procedure

For deriving the required burden estimates, estimates of the μ_i and σ_i^2 parameters are needed. Based on the $x_{i1}, x_{i2}, \ldots x_{i\,n_i}$ assay data, these estimates can be directly derived (the equivalence between the surface area element and coupon area size is noted). The estimates, represented as $\bar{x}_i$ and s_i^2 respectively in Table 4, are calculated as follows:

$$(5)\quad \bar{x}_i = \sum_{j=1}^{n_i} x_{i\,j} / n_i$$

and

$$(6)\quad s_i^2 = \left\{ n_i \sum_{j=1}^{n_i} x_{i\,j}^2 - \left(\sum_{j=1}^{n_i} x_{ij} \right)^2 \right\} / n_i\,(n_i - 1$$

The best estimate of the total microbial burden of the i^{th} subpopulation can be derived as follows:

$$(7)\quad b_i = N_i\,\bar{x}_i$$

where b_i denotes the best estimate of B_i.

An upper bound estimate (90 percent confidence) of B_i can be derived as follows:

$$(8)\quad \breve{b}_{i,\,.90} = b_i + ts_{b_i}$$

where $\breve{b}_{i\,.90}$ denotes an upper 90 percent confidence limit estimate of B_i, i.e., a burden value bound which will exceed B_i with probabilit .90 under the assumptions of the analysis.

t= a statistical tabular factor, i.e., "Student" t table.

$$s^2_{b_i} = \left(N_i^2 \, s_i^2/n_i\right)\left(1 - \frac{n_i}{N_i+n_i}\right)$$

The best estimate of the total microbial burden (B_t) can be derived as follows:

$$(9) \quad b_t = \sum_{i=1}^{k} N_i \, \bar{x}_i$$

where b_t denoted the best estimate of B_t.

An upper bound estimate (90 percent confidence) of B_t can only be approximated for k>1 (for the case, k = 1, the $\breve{b}_{i,\ .90}$ estimate would apply). The suggested approximation to be used is as follows:

$$(10) \quad \breve{b}_{t,\sim.90} = \sum_{i=1}^{k} N_i \, \bar{x}_i + t' \left(\sum_{i=1}^{k} s_{b_i}^2\right)^{\frac{1}{2}}, \ (k>1)$$

where $\breve{b}_{t,\sim.90}$ denotes the approximate upper 90 percent confidence limit estimate of B_t.

$$t' = \sum_{i=1}^{k} s_{b_i}^2 \, t_{i.,\ .90} \Big/ \sum_{i=1}^{k} s_{b_i}^2, \ (k>1)$$

where $t_{i,\ .90}$ = the statistical tabular factors used in deriving $\breve{b}_{i,\ .90}$.

An important assumption in the above analysis plan relates to the distribution form of the true burden values of the surface area elements in the respective subpopulations. The assumption is that these distribution forms are in accordance with the familiar Gaussian, i.e., bell-shaped or normal, Distribution Model. A prerequisite requirement of the presented analysis plan is therefore, to perform preliminary evaluations relative to the experimental assay data derived for determining whether the distribution form assumption is reasonable.

In outlined form, the preliminary evaluations can be performed as follows:

1. For the larger samples of the respective subpopulations, i.e. $n_i > 30$, prepare tables of the respective groups of assay data in original units of measurement, i.e. number of organisms per coupon, and several transformations of these values, i.e. logarithmic, square root, arcsine, etc.

2. For the respective groups, plot the data on normal probability graph paper. Normality would be indicated if the respective groups of data of similar measurement units (transformed or untransformed), plot reasonably straight.

3. If the above procedure does not lead to a reasonable conclusion, more sophisticated methods can be used, i.e. Bartlett's Goodness of Fit Test, etc. (see references).

The presented analysis plan can be directly implemented whether the coupon assay data is in original measurement units or converted by some appropriate transformation. In the latter case, the only additional requirement, other than performing the transformations of the experimental assay data generated in the experiment, is to perform the reverse transformation on all final estimates derived in the analyses.

It is noted that the above analysis plans relate solely to deriving burden estimates at the respective nine assembly stages, and do not relate to statistical comparasions of these various estimates.

C. References

(1) Statistical Methods Applies to Experiments in Agriculture and Biology, George W. Snedecor, Iowa State College Press, Ames Iowa, Fifth Edition.

(2) Experimental Designs, William G. Cochran and Gertrude M. Cos, John Wiley & Sons, Inc., Second Edition.

(3) Statistical Analysis in Chemistry and the Chemical Industry, C.A. Bennett and N.L. Franklin, John Wiley & Sons Inc., 1954

VIII Illustrative Example

For further clarifying the presented procedures and tables, the following series of steps which would lead to burden estimates at Estimation Point #3 in the CMTM assembly is given:

1. The requirement to derive burden estimates at Estimation Point #3 is identified by the coupon removal operation specified in Section 2.0 Operation 50 of Appendix A. (CMTM Assembly Procedure).

2. The number and identification of the coupons to be removed at Estimation Point #3 are specified in Appendix C (Coupon Removal Schedule). Thus, one hundred eight (108) coupons are identified to be removed for assay, i.e. A01-10, A01-12., -------- U03-09. Also identified are the 64 dummy coupons to be removed, i.e., two A09 coupons, one B02 coupon, etc. Since the latter represent all remaining coupons in a given area segment, their identification is established.

3. The location of the coupons to be removed at Estimation Point #3 is established with an understanding of the five character code system used for coupon identification (see V-C), and the information provided in Appendix G. For example, the A01-10 coupon is located as follows, (a) the first character in the identification code is A, therefore an Aeroshell drawing in Appendix G is indicated, and (b) the remaining characters in the identification code is 01-10 which would be included in the "coupon distribution" information provided in the specific Aeroshell drawing which locates the coupon.

4. The data derived from the assays performed on the coupons removed at Estimation Point #3 would be recorded on data forms as suggested in Appendix F. The data would be subsequently screened, reduced and compiled for analysis by the methods given in the analysis plan (see VII-B, i.e., x number of organisms per Estimation Point #3 coupons assayed by zone category (subpopulation).

5. Assuming that the assay data, in original or transformed measurement units, meet the statistical assumptions of normality (see Page 24), the average ($\bar{x}$) and standard deviation (s) estimates would be derived for the respective zone categories of Estimation Point #3 in accordance with equations (5) and (6).

6. The best estimate and the 90 percent confidence upper bound estimate of the respective zone category burdens at Estimation Point #3 in accordance with equations (9) and (10) respectively.

7. The best estimate and the 90 percent confidence upper bound estimate of the defined total burden at Estimation Point #3 would be derived in accordance with equations (9) and (10) respectively.

NOTE: It is noted that in Step 2 above, Appendix C is referenced for specifying the identity of the coupons to be removed at Estimation point #3. The information of Statistical Table 4-3, Appendix B, and Appendix E are consistent with these coupon identifications.

Statistical Table (4-3) shows the basic final allocation of coupons to be assayed at Estimation Point #3 by zone category, i.e., seven (7) for the A-1 zone category, seven (7) for the A-2 zone category, etc. The total of these allocations is one hundred eight which is consistent with the number of coupons to be removed for assay shown in Appendix C.

Similarly, Appendix B shows the basic apportionment of the assay coupons allocated for Estimation Point #3 among the area segments which comprise the various zone categories. For example, the seven (7) coupons allocated for the A-2 zone are shown to be apportioned as follows: five (5) for the D01 area segment and one (1) for each of the D06 and S07 area segments. Appendix B also shows the number of dummy coupons to be removed at Estimation Point #3. It is noted that in the summary portion of Appendix B, the total number of coupons to be assayed, i.e., 108, and the total number of dummy coupons to be removed, i.e., 64 are consistant with Appendix C.

Appendix E shows the disposition of the entire thirteen hundred ninety (1390) assay and dummy coupons used in a given CMTM assembly. Accordingly, the consistency of Appendix E and Appendix C is shown by the correspondence of the coupons to be removed for assay and the dummy coupons to be removed at Estimation Point #3 shown in these two appendices.

Appendix A

SUGGESTED CMIM ASSEMBLY PROCEDURE

(REF. JPL PROCEDURE CMIM 100.01)

CMTM PREPARATIONS

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATION
A				Acceptance test of subassemblies.
A.1				Estimation of microbial load.
A.2			2 Bio.	Placement of coupons on surfaces of subassemblies. Following the maps of Appendix G, attach 1" x 2" 0.06 stainless steel strips to the prescribed location by means of double sided sterile tape. Each strip is to be identified by subassembly, zone, and coupon numbers and is to be sterilized prior to placement.
A.3				Procedure for TA/FA.
B				Clean subsystems to class 100 level.
B.1				ETO CYCLE. Submit the following subassemblies to the ETO chamber for a 24-hour cycle: 7 Dummy chassis. Data encoder. Payload structure assembly & dolly. Impact limiter & dolly. Band assembly clamp & c-clamp handles. Parachute canister & dolly De-orbit motor & dolly. Motor clamp assembly Relay link antenna assembly. Jack stands. Jack extensions. Adjustable jacks. Remove all parts into SADL.

CMTM PREPARATIONS - cont'd

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
B.2				ETO CYCLE Submit the following subassemblies to the ETO chamber for a 24-hour cycle: Aeroshell & dolly Two stools. Remove all parts into SADL.
B.3				ETO CYCLE Submit the sterilization canister to the ETO chamber for a 24-hour cycle.

Section 1.0 (Assembly of Chassis)

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
5			2 Bio Technicians 1 QA Inspector	Removal of coupons. Estimation Point 1 When the parts from the first ETO cycle (B.1) enter the SADL, remove for assay those coupons designated for removal by the schedule of Appendix C.
			2 Assem. 2 Inspectors	Receive tools into SADL.
10	Torque wrench (6-15"#) Allen type sockets 1/4" socket wrench Payload Dolly	Payload structure mounted on Payload dolly. 8 chassis (182) 8-32 x 1/2" lg. st. stl. soc. hd. screws. (26) 8-32 x 1" st. stl. soc.hd. screws.	2 Assem. 2 Insp. 1 Bio.	Position Bus Section and Payload Dolly in southeast corner of Assembly Area. Quality Assurance - shall verify that the Bus Section and Payload Dolly have been positioned in the southeast corner of the Assembly Area.

Section 1.0 (Assembly of Chassis) cont'd.

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
20	Same as Op. #10	Same as Op. #10	Same as Op. #10	Remove dummy outer covers, secured with 8-32 x 1/2 screws and store. Remove inner cover plate of Bay VIII.
35	"	"	"	Quality Assurance - shall visually verify that the eight dummy outer panels, (one from each bay) and one inner cover plate from bay VIII have been removed.
40	"	"	"	Using handles provided, position DATA ENCODER Chassis in Bay VIII. Install (26) 8-32 x 1" soc. hd. cap. screws. Make harness connections for DATA ENCODER by mating connectors of the test cable to the brackets which are attached to the motor support ring. Torque screws 6-8 in. lbs.
45	"	"	"	Prior to chassis installation, Quality Assurance shall assure that each bay in the structure is clean and free of any loose hardware or foreign materials. Quality Assurance shall witness the mating of five (5) connectors of the test cables. Quality Assurance shall assure that the screws protrude thru the nuts by one (1) to one and one-half (1-1/2) threads.
60	"	"	"	Install (7) dummy chassis in remaining bays, using hardware removed from dummy covers in Operation 20.

Section 1.0 (Assembly of Chassis) cont'd.

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
65	Same as Op. #10	Same as Op. #10	Same as Op. #10	Quality Assurance - shall assure that the correct type and quantity of fastener screws have been installed on all chassis assembly.
70	"	"	"	Torque all screws to AF SCM 80-8 Specifications. 12-15 in. lbs.
75	"	"	"	Quality Assurance - shall verify that the torque wrench is within calibration. Quality Assurance shall witness and record the torque of the 8-32 screws to the torque values specified in AF SCM 80-8 Specifications. 12-15 in. lbs.
85	"	"	"	Position Payload Dolly under #2 hook and perform simulated systems test per testing and calibration instructions. EPD #85 Rev. 1 and Addendum 1. NOTE: Go through step by step procedure. Equipment Need Not Function. Remove tools for sterilization.
90	"	"	2 Bio. Technicians 1 QA Inspector	Estimation Point 2. Remove coupons designated for removal by the schedule of Appendix C.

Section 2.0 (Assembly of Impact Limiter)

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
				Receive tools into SADL.
10	Impact limiter sling	Support structure mounted on dolly.	2 Assem.	Remove Payload dolly from under #2 hook and attach Hydraset.
			2 QA Insp.	Position the Impact Limiter and dolly under the #2 hook.
	Limiter dolly.	Impact Limiter	1 Bio.	Quality Assurance shall inspect the Impact Limiter to the extent necessary to assure that wires are not broken, damaged or pulled from the thermo-couples.
	Template gauge .220 dim. Hydraset.			The wires shall be taped to the upper half and exterior to the spherical.
20	"	"	"	Attach the Limiter Sling to the Impact Limiter and Hook.
25	"	"	"	Quality Assurance shall verify that the Impact Limiter Sling has physical evidence of proof test and is within its proper cycle.
30	"	"	"	Raise the Limiter to a height sufficient to allow removal of the Limiter Dolly and replace-ment by the Payload Dolly with Payload.

Section 2.0 (Assembly of Impact Limiter) cont'd.

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
35	Same as Op. #30	Same as Op. #30	Same as Op. #30	Quality Assurance shall inspect the bonded silicone rubber cushions (4) to assure that they are properly installed and bonded into position within the Impact Limiter Support Structure.
40	"	"	"	Lower Impact Limiter to rest on pads in support structure, using Hydraset as necessary, remove sling.
45	"	"	"	Quality Assurance shall inspect for correct clearance between the Impact Limiter and the Impact Limiter Support Structure after the Limiter has been lowered into position. Remove tools for sterilization.
50	"	"	2 Bio. Technicians 1 QA Inspector	Estimation Point 3. Remove coupons designated for removal by the schedule of Appendix C.

Section 3.0 (Assembly of Aeroshell)

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
				Receive tools into SADL.
10 thru 50	Fixture hoisting	Aeroshell & dolly.	2 Assem. 2 QA Inspectors	Move Payload with Dolly from under Hook and set to one side.
	CMTM Canister Assy.	Payload, etc. mounted on dolly.	1 Bio.	Position Aeroshell with dolly under the #2 Hook and attach hoisting fixture 1000 2314.
	Jack stands Jack extensions	Clamp assy.		Quality Assurance shall verify that the Aeroshell Sling has physical evidence of proof test and is within its proper cycle.
	Adjustable jacks.			Remove (6) tie-down bolts and raise Aeroshell sufficiently to allow Aeorshell Dolly to be removed and replaced with the Payload with Dolly.
	3/4" open-end wrench 3/4" crow foot wrench Torque wrench (160-190"#). Allen wrench Stools (2).			Position (3) jacks under Aeroshell and lower Aeroshell into position on the Payload with hoist and Hydraset, adjusting jacks as necessary to accomplish proper mating.

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
55	Same as 50	Same as 50	Same as 50	Quality Assurance shall monitor and verify the lowering of the Aeroshell to the Payload Assembly to assure that the Aeroshell is properly levelled on the three (3) jacks and that it is properly aligned with the 000° reference. Quality Assurance shall perform a visual inspection to ensure that the mating flanges of the spacer rings are properly mated.
60	"	"	3 Assem. 1 QA Inspector 1 Bio.	Installation of Clamp assembly. Position two stools 180° apart under the Aeroshell so that they are located in a manner to position the clamp assembly. Using the stools provided, two assemblers will position the clamp in its proper location. (In order to reduce handling contact, the c-clamps will be used as handles by the assemblers.) The third assembler will torque the band assembly clamp to #AF SCM 80-8 specifications. 160-190 in. lbs.

Section 3.0 (Assembly of Aeroshell)

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
65	"	"	"	Remove the c-clamps. Quality Assurance shall inspect the installation of the securing ring clamps for correct installation and torque requirements. Remove the c-clamps from SADL.
70	"	"	"	Reposition the stools under the attitude control tanks. Make cabling and plumbing connections as required.
75	"	"	"	Quality Assurance shall inspect to ensure complete installation and connection of electrical cables and plumbing. One assembler will leave the SADL with the two stools.
80 and 85	"	"	2 Assem. 2 QA Inspectors 1 Bio.	Remove (8) alignment clips (16 10-32 soc. hd. cap screws) from Payload Section and raise Assembly clear of Payload Dolly with Hoisting fixture 1000 2314. Remove Payload Dolly and lower Aeroshell to jacks. Quality Assurance shall verify that all alignment clips have been removed prior to raising Payload Structure. Remove tools from SADL.
90	"	"	2 Bio Tech. 2 QA Insp.	Estimation point 4. Remove coupons designated for removal by the schedule of Appendix C.

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
				Receive tools into SADL.
10 thru 25	Hoisting fixture De-orbit Motor Installation fixture Pedestal assembly Allen wrench (6"). Torque wrench (40-50"#).	Parachute Canister & Dolly. Six 1/4-20 x 3/4" lg. socket head screws Six 1/4" Nom. flat washers.	2 Assem. 2 QA Insp. 1 Bio.	Attach the Pedestal Assembly 1000 8868 to the De-orbit Motor installation fixture 1000 2302. Place the Parachute Canister on the top plate of the pedestal and properly align the hole pattern. Quality Assurance shall inspect for correct hole alignment.
30	"	"	"	Position the dolly under the Payload/Aeroshell Assembly and raise pedestal to mate the Parachute Canister with the Motor Support structure.
40	"	"	"	Install (3) 1/4 .20 x 3/4" screws through the fixture clearance holes (.7000 dia.) and tighten.
45	"	"	"	Quality Assurance shall inspect for proper installation 45° of the Parachute Canister to the Motor Support Structure Ring. 000° reference alignment shall also be established.

Section 4.0 (Assembly of Parachute Canister) cont'd.

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
50	Same as Op. #45	Same as Op. #45	Same as Op. #45	Lower the pedestal assembly and remove the De-orbit Motor Dolly.
60	"	"	"	Install (3) remaining 1/4-20 screws with the required washers in the Parachute Canister and tighten. Remove (3) screws initially installed without washers. Add washers and replace in Canister.
65	"	"	"	Quality Assurance shall verify that the correct quantity and type of screws and washers have been installed.
70	"	"	"	Torque all screws to #AP SCM 80-8 specifications. 40-50 in. lbs.
75	"	"	"	Quality Assurance shall verify the calibration date of the torque wrench. Quality Assurance shall witness and record the action that the screws have been torqued to the correct requirements as specified in the AF SCM 80-8 Specification. Remove tools from SADL.
80	"	"	2 Bio. 2 QA Insp.	Estimation point 5. Remove coupons scheduled for removal per the schedule of Appendix C.

Section 5.0 (Assembly of De-orbit Motor)

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
				Receive tools into SADL
10 thru 40	Hoisting Fixture 1/4" Allen wrenchs Torque wrench (12-15"#)	De-orbit Motor Motor Clamp Jack Stands Jack Extensions	2 Assem. 2 QA Inspectors 1 Bio.	Remove Pedestal Assembly 1000 8838 from De-orbit Motor installation fixture. Place the De-orbit Motor in the nest of the Dolly Pallet, and position the dolly under the Payload/Aeroshell Assembly.
	Motor installation fixture 1/4" Socket with ratchet	Jacks		Raise the De-orbit Motor to the mating surface of the Motor Support structure and install clamp assembly 1000 8874. Remove dolly.
45	"	"	"	Quality Assurance shall verify proper installation of the clamp assembly and visually verify that the alignment is correct.
50	"	"	"	Torque Clamp Assembly to AF SCM 80-3 Specification. 12-15 in. lbs.
55	"	"	"	Quality Assurance shall witness the torque action of the clamp assembly. Remove tools from SADL
60	"	"	2 Bio. Tech. 2 QA Inspectors	Estimation point . Remove coupons scheduled for removal by the schedule of Appendix C.

Section 6.0 (Assembly of Relay Antenna)

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
				Receive tools into SADL
10 and 15	Hoisting fixture. 6" socket exten. 3/8 drive with ratchet Allen type socket wrench Torque wrench (20-25"#)	Relay Link Antenna (3) 10-32 x 1/2 soc. hd. cap screws. (3) MS16999-16 Jack stands Jack extensions Jacks	2 Assem. 2 QA Inspectors 1 Bio.	Mate Relay Antenna 1000 8870 to lower surface of Bus Section at Bay III and install (3) 10-32 screws. Quality Assurance shall verify the proper installation and orientation of the Relay Link Antenna to the lower surface of the Payload Assembly.
20	"	"	"	Torque screw to AF SCM 80-8 Specifications, 20-25 in. lbs.
25	"	"	"	Quality Assurance shall witness the torque action of the 10-32 screws to the AF SCM 80-8 specification. Remove tools from SADL
30	"	"	2 Bio. Techs. 2 QA Inspectors	Estimation point 7. Remove coupons scheduled for removal by the schedule of Appendix C.

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
				Enter canister and dolly into SADL from ETO Chamber.
				Receive tools in SADL.
10 thru	Hoisting Fixture	Canister & Dolly	2 Assem. 2 QA Insp.	Attach Hydraset to #1 hook amd remove Canister/ Dolly from ETO chamber and position under #1 hook using power hand truck.
25	Allen wrench 3/8 drive w/ratchet. 9/16 soc. wrench 3/8 ratchet for cover removal. Hydraset Torque wrench (160-190"#)	(8) 3/8 - 24 bolts with O-rings, (soc. hd.)	1 Bio.	Attach Hoisting Fixture 1000 2314 to Canister Cover. Quality Assurance shall verify that the Canister Cover Sling has physical evidence of proof-test and that it is within its proper cycle.
30	"	"	"	Remove (38) 3/8-24 & (2) 1/2 - 20 hex hd. bolts.
40	"	"	"	Disassemble the umbilical cover plate with "O" ring by removal of (8) 3/8 - 24 bolts.

Section 7.0 (Assembly of CMTM in Canister) cont'd.

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
50	Same as Op. #40	Same as Op. #40	Same as Op. #40	Raise the CMTM Assembly on the #2 hook and remove the (3) jacks.
60	"	"	"	Raise the Canister Cover on the #1 hook; remove the Canister/Dolly and reposition under the CMTM on #2 hook. (Leave Canister Cover suspended on #1 hook).
70	"	"	"	Lower the CMTM Assembly into the Canister orienting the X & Y axes properly using hoist & hydraset and simultaneously guide the capsule harness through the umbilical opening.
75	"	"	"	Quality Assurance shall verify that the CMTM Assembly is properly lowered into the Canister dolly and properly oriented with the X and Y axes, In addition, verify that the umbilical harness is properly guided through the umbilical opening.
80	"	"	"	Install (6) tie-down screws to Aeroshell and remove sling.
90	"	"	"	Torque screws to #AF SCM 80-8 Specifications. 160-190 in. lbs.
95	"	"	"	Quality Assurance shall verify that the six (6) screws have been installed and shall witness the torque action to the proper torque value as specified in AF SCM 80-8. Remove tools from SADL.

Section 8.0 (Assembly of Umbilical)

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
10	9/16" socket 3/8 drive socket wrench 3/8 drive 6" extension Torque wrench (160-190"#)		2 Assem. 2 QA insp. 1 Bio.	Receive tools into SADL Pass umbilical plate "O" ring over all CMTM Harness connectors previously guided through canister umbilical opening.
20	"		2 Bio. Tech. 2 Assem. 2 QA Insp.	Estimation point 8. Mate all harness and umbilical plate connectors. Remove coupons per the schedule of Appendix C.
25	"		2 Assem. 2 QA Insp. 1 Bio.	Quality Assurance - shall inspect the adequacy of all the umbilical harness connectors.
30	"		"	Position "O" ring properly in its groove and replace umbilical plate on canister mounting surface, securing it with (8) 3/8 - 24 hex. hd. bolts.

Section 8.0 (Assembly of Umbilical) cont'd.

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
35	Same as Op. #30	Same as Op. #30	Same as Op. #30	Quality Assurance - shall perform inspection for proper installation of positioning the "O" ring in the groove.
40	"	"	"	Torque bolts to AF SCM 80-8 specifications. 160-190 in. lbs.
45	"	"	"	Quality Assurance shall witness the torque action of the (8) - 24 bolts securing the umbilical cover plste. Remove tools from SADL.

Section 9.0 (Systems Test)

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
10			2 Bio. Tech. 2 QA Inspectors	Test per EPD #85 Rev. 1 and Addendum 1. Estimation point 9 Remove coupons scheduled for removal by the schedule of Appendix C.

Section 11.0 (Assembly of Canister Cover)

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
10 thru 25	Hand power truck Wrenchs: 9/16 soc. w/ratchet and ext. 6" torque Hoisting fixture Hydraset Torque wrench (250-350"#) 3/4" socket	Canister Cover CMTM Assy in canister Hex hd. bolts (38) 3/8 - 24 3/8 flat washers (38) (2) 1/2 -20 hex. hd. bolts. (2) 1/2 flat washers (special)	2 Assy. 2 QA Inspectors 1 Bio.	Using power hand truck, position Canister under the cover suspended on the #1 hook. Install Canister "O" Ring. Quality Assurance shall verify the installation of the "O" ring into the canister mating ring groove.
30	"	"	"	Rotate to proper "O" orientation and lower Canister cover to the mating surface of the Canister.
40	"	"	"	Install (38) 3/8 - 24 & (2) 1/2 - 20 hex hd. bolts with washers.
50	"	"	"	Torque all bolts, applying torque in 50"# increments. 3/8 - 24 bolts - 250 in. lbs., 1/2 - 20 bolts - 350 in. lbs. Torque sequence should be staggered 180° apart & torque applied simultaneously.

Section 11.0 (Assembly of Canister Cover) cont'd

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
55	"	"	"	Quality Assurance shall verify torque wrench calibration and witness the torque action of the 40 bolts to JPL Engineering direction. Remove tools from SADL.

Section 12.0 (CMTM Sterilization)

OPER. #	TOOLS & EQUIPMENT	HARDWARE	PERSONNEL	OPERATIONS
10 thru 35			2 Assem. 2 QA Insp. 1 Bio.	Using the power hand truck, remove the canister from the SADL and position the canister in the oven chamber. Remove casters if necessary, and cycle as required. Quality Assurance shall verify heat cycling and time of exposure and temperature control. Quality Assurance shall verify the calibration of instruments, gauges and recorders prior to monitoring the heat sterilization of the CMTM.
40			"	Following heat cycles, reassemble casters and return canister to work area.

APPENDIX B

DESCRIPTIONS OF SURFACE AREAS, ZONES, AND COUPON QUANTITIES.

CMTM STERILIZATION PROGRAM

DEFINITION OF ZONES AND COUPON QUANTITIES

CLASSIFICATION OF ZONES:

A-1. Heavy burden, initially handled area.

A-2. Heavy burden, area handled in previous assembly stage.

A-3. Heavy burden, area handled two assembly stages earlier.

A-M. Heavy burden, area handled M-1 assembly stages earlier.

B. Moderate burden, direct fallout, horizontal upward flat surface, ridges, flanges.

C. Light burden, indirect fallout, vertical or slanted surfaces.

D. Very light burden, downward or inside surfaces.

M. Mates Surfaces.

O. Occluded Surfaces.

I. Inaccessible surfaces, not occluded or mated.

NOTE:

1. The numbers of dummy coupons, which are to be removed but not assayed, appear in parentheses.

2. An asterisk (*) indicates where a zone is handled just prior to the corresponding estimation point.

3. Surface **area** values which were estimated without measurements are denoted by the letter E.

4. Definitions of estimation points appear in Section II B of the text. (Part 4)

CMTM STERILIZATION PROGRAM

DEFINITIONS OF ZONES AND COUPON QUANTITIES
(See explanatory notes on Page 1 of this Appendix)

Part	Zone	Surface Area ($In.^2$)	Description of Area	Quantity of coupons to be removed and zone classification at each estimation point.									Total Coupon Quantity
				1	2	3	4	5	6	7	8	9	
Aeroshell	A01	25,345	Outside surface including the apex and conic section (Frustum)	5 D	0 C	17 C	0 C	17 C	0 C	16 C	0 C	24 (131) C	210
Aeroshell	A02	12,700	Outside surface cylindrical section. Subject to less fallout than zone 1, but there is a higher probability of human contamination, e.g., from coughing, sneezing, and accidental handling	3 D	0 C	8 C	0 C	9 C	0 C	9 C	0 C	10 (69) C	108
Aeroshell	A03	406.	Internal support ring cylinder, outside surface, y ± 45° sector.	1 D	0 D	1 D	3 * A-1	2 A-2	1 A-3	2 (20) A-4	0 0	0 0	30
Aeroshell	A04	406.	Internal support ring cylinder outside surface X ± 45° sector.	1 D	0 D	1 D	2 * A-1	2 A-2	2 A-3	2 (22) A-4	0 0	0 0	32
Aeroshell	A05	406.	Internal support cylinder outside surface, -y ± 45° sector.	0 D	0 D	1 D	2 * A-1	2 A-2	I A-3	2 (22) A-4	0 0	0 0	30
Aeroshell	A06	406.	Internal support ring cylinder outside surface, - X ±45° sector.	0 D	0 D	1 D	2 * A-1	3 A-2	2 A-3	1 (21) A-4	0 0	0 0	30

CMTM STERILIZATION PROGRAM

DEFINITIONS OF ZONES AND COUPON QUANTITIES
(See explanatory notes on Page 1 of this Appendix)

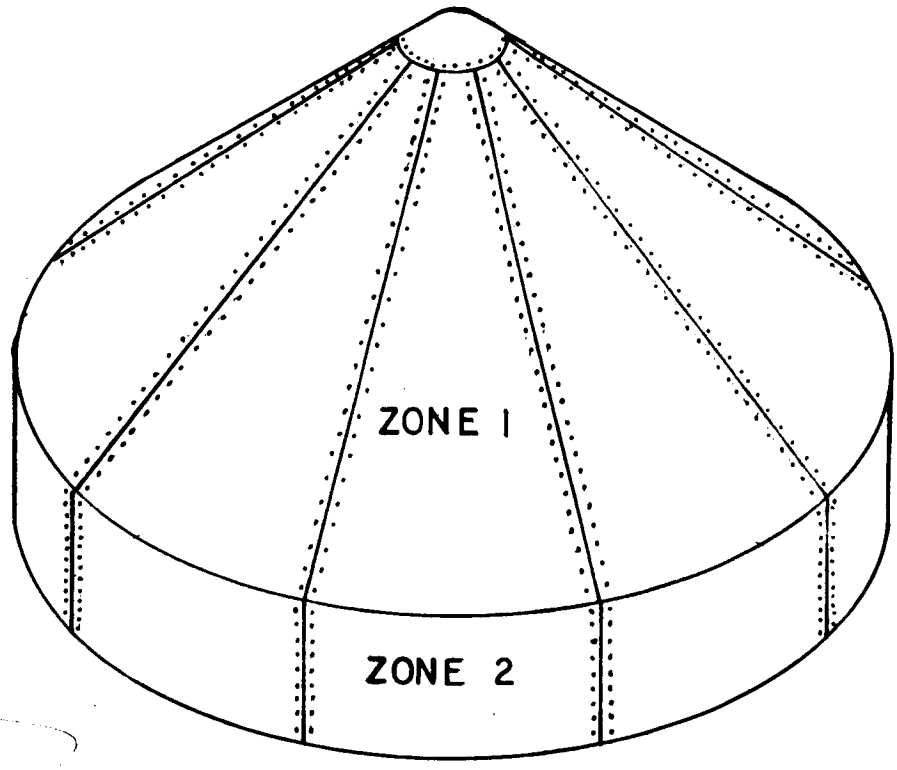
Part	Zone	Surface Area ($In.^2$)	Description of Area	Quantity of coupons to be removed and zone classification at each estimation point.									Total Coupon Quantity
				1	2	3	4	5	6	7	8	9	
oshell	A07	4084	Internal support ring cylinder inside surface (360°) and inside of flange, plus portion of inner surface of shell bounded by the cylinder	1 (2) D	0 D	0 D	0 0	0 0	0 0	0 0	0 0	0 0	3
oshell	A08	373	Internal support ring flange top and edge, plus connectors and brackets.	0 D	0 D	0 D	0 * 0	0 0	0 0	0 0	0 0	0 0	0
oshell	A09	287	Internal support ring flange bottom.	0 D	0 D	1 (2) D	0 M	0 M	0 M	0 M	0 M	0 M	3
oshell	A10	20,000	Inside surface of shell, excluding portion bounded by internal support ring cylinder at the apex of the shell.	4 D	0 D	5 D	0 D	8 D	0 D	10 (63) D	0 0	0 0	90
oshell	A11	16,960	Inside surface of shell, cylindrical section, plus bottom of aeroshell.	3 D	0 D	5 D	0 C	11 C	0 C	11 (60) C	0 0	0 0	90
oshell	A12	1378	Both shells around attitude control tanks including the support brackets and electrical connectors.	0 D	0 D	1 D	0 D	1 D	0 D	2 (6) D	0 0	0 0	10

CMTM STERILIZATION PROGRAM

DEFINITIONS OF ZONES AND COUPON QUANTITIES
(See explanatory notes on Page 1 of this Appendix)

Part	Zone	Surface Area ($In.^2$)	Description of Area	Quantity of coupons to be removed and zone classification at each estimation point.									Tot Cou Qua
				1	2	3	4	5	6	7	8	9	
Aeroshell	A13	1464	Two spherical attitude control tanks.	1 D	0 D	1 D	0 D	1 D	0 D	1 (8) D	0 0	0 0	12
Aeroshell	A14	3000[E]	Mated and fayed surface areas (total) (X 2)	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0
Aeroshell	A15	1625[E] (a) X (b) = 1625 $inches^2$	(a) Total number of rivets = 3620. (b) Total mated surface contact area per rivet (X2) = 0.45 (average).	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0
Aeroshell	A16	190[E]	Cabling and Piping.	0 D	0 D	0 D	0 C	1 C	0 C	1 (8) C	0 0	0 0	10

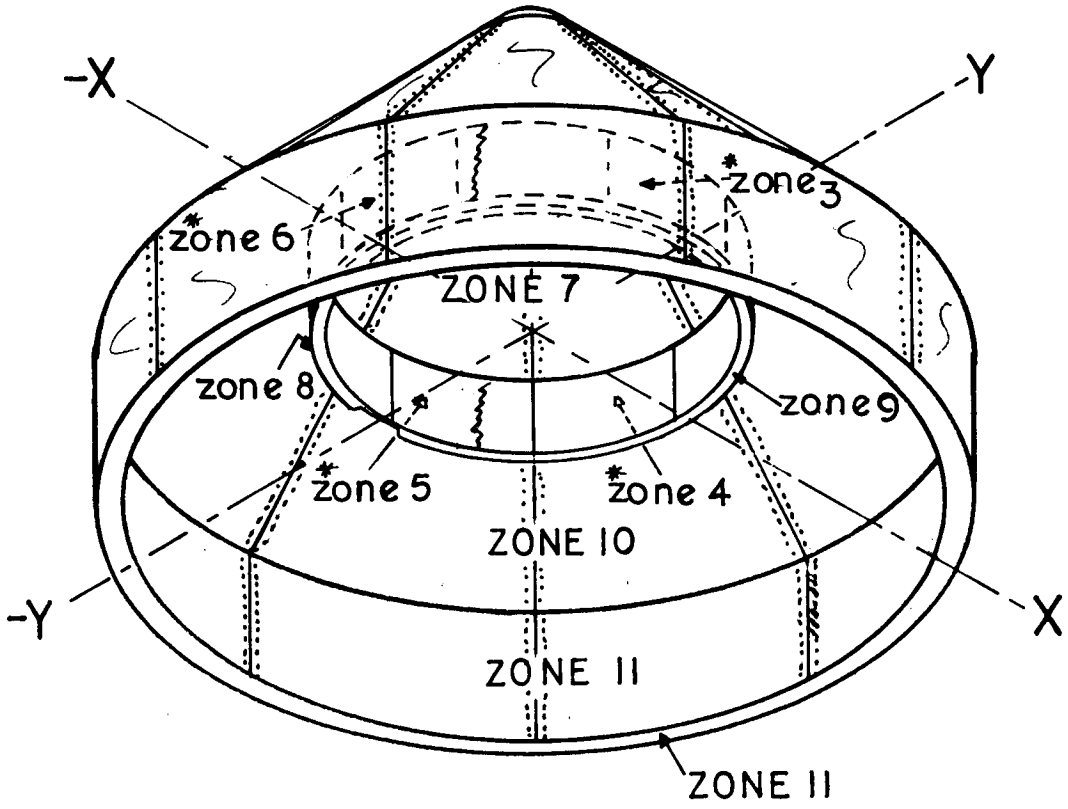
AEROSHELL



OUTSIDE SURFACE

Figure 4-2 ZONE DEFINITION - AEROSHELL OUTSIDE SURFACE

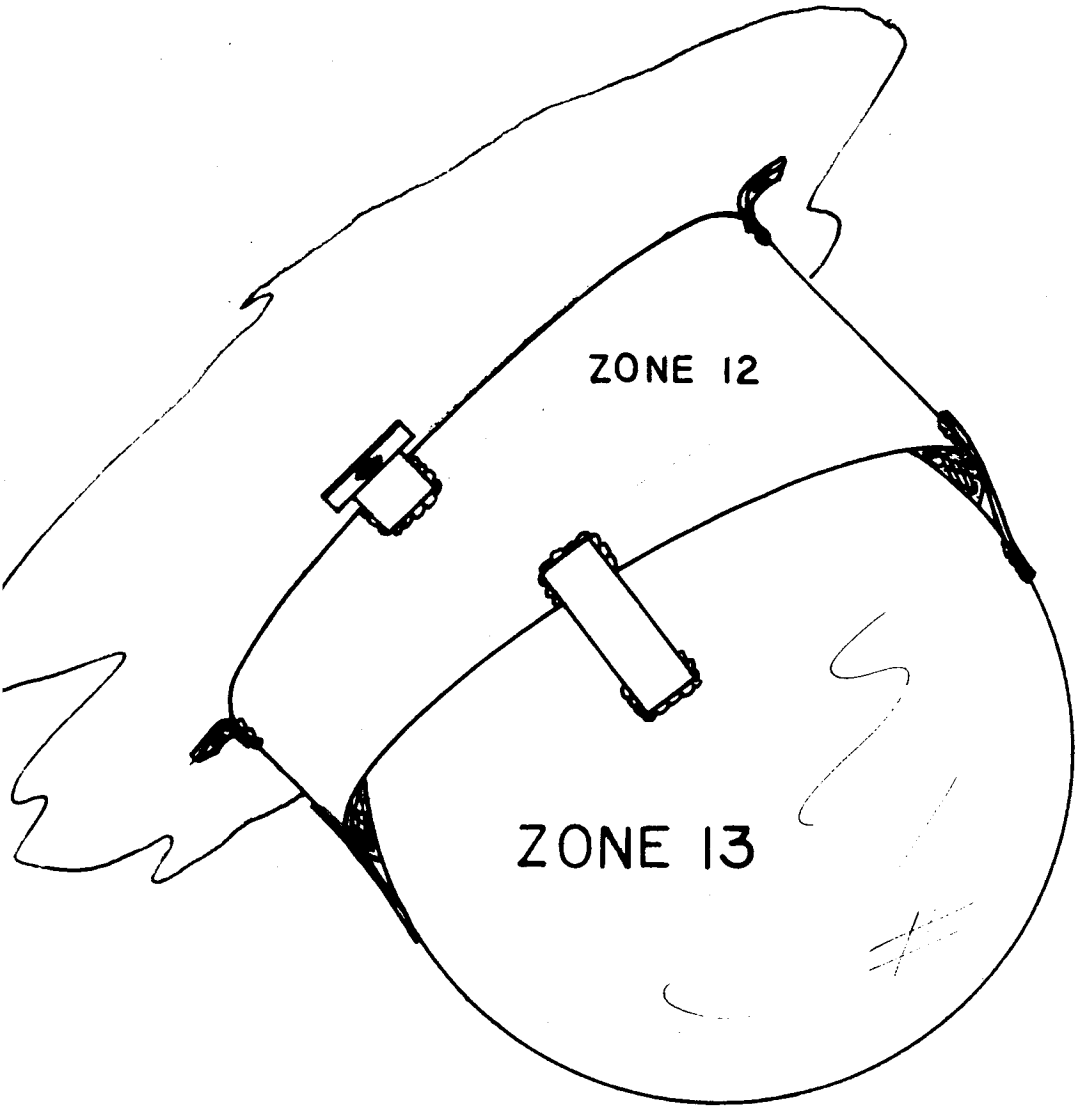
AEROSHELL (INSIDE VIEW)



*ZONES 3,4,5 & 6 outside surface of inner ring as pictured

Figure 4-3 ZONE DEFINITION - AEROSHELL INNER SURFACE

AEROSHELL (ATTITUDE CONTROL SYSTEM)



2 BOTTLES AT $X\acute{\epsilon}$-X AXIS AS PICTURED

Figure 4-4 ZONE DEFINITION - AEROSHELL - ATTITUDE CONTROL SYSTEM

CMTM STERILIZATION PROGRAM

DEFINITIONS OF ZONES AND COUPON QUANTITIES
(See explanatory notes on Page 1 of this Appendix)

Part	Zone	Surface Area ($In.^2$)	Description of Area	Quantity of coupons to be removed and zone classification at each estimation point.									Total Coupon Quanti
				1	2	3	4	5	6	7	8	9	
Clamp	B01	810.	Outside and edges of clamp.	0 D	0 D	2 D	2 * A-1	2 A-2	2 A-3	1 (11) A-4	0 0	0 0	20
Clamp	B02	462.	Inside and Backface.	0 D	0 D	3 (1) D	0 * 0	0 0	0 0	0 0	0 0	0 0	4
Clamp	B03	68. E	Support clips turnbuckle, nut & swivel bolts.	0 D	0 D	0 D	1 * A-1	0 A-2	1 A-3	0 A-4	0 0	0 0	2
Clamp	B04	540. E	Occluded areas behind support band.	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0

CMTM STERILIZATION PROGRAM

DEFINITIONS OF ZONES AND COUPON QUANTITIES
(See explanatory notes on Page 1 of this Appendix)

Part	Zone	Surface Area ($In.^2$)	Description of Area	Quantity of coupons to be removed and zone classification at each estimation point.									Total Coupon Quantity
				1	2	3	4	5	6	7	8	9	
erili- tion nister	C01	E 150.	Interior of umbilical port	0 D	0 D	0 D	0 D	1 D	0 D	0 D	2 (1) * A-1	0 0	4
erili- tion nister	C02	E 40,000	Interior of top of canister.	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 D	12 (12) D	24
erili- tion nister	C03	E 30,000.	Interior of bottom of canister. (This is exposed to atmosphere for a very short time only).	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0
erili- tion nister	C04	2800	Mating flange of top of canister.	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0 D	12 (18) D	30
erili- tion nister	C05	2800.	Mating flange of bottom of canister (although this faces upward horizontally, it is exposed to the atmosphere for a very short time only).	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0 C	10 (20) C/O	30

CMTM STERILIZATION PROGRAM

DEFINITIONS OF ZONES AND COUPON QUANTITIES
(See explanatory notes on Page 1 of this Appendix)

Part	Zone	Surface Area ($In.^2$)	Description of Area	Quantity of coupons to be removed and zone classification at each estimation point.									Total Coupon Quantit
				1	2	3	4	5	6	7	8	9	
Dummy Chassis & Data Encoder	D01	392.	Handled areas on panels of the 7 dummy chassis 2 x 7 x (7 x 4) = 392 Sq. inches	0 D	4 * A-1	5 A-2	3 A-3	4 A-4	5 A-5	6 (57) A-6	0 0	0 0	84
Dummy Chassis & Data Encoder	D02	2180	Unhandled portion of the front panels of the 7 dummy chassis and edges of exposed panels	2 D	0 C	17 C	0 C	13 C	0 C	15 (23) C	0 0	0 0	70
Dummy Chassis & Data Encoder	D03	320	Portions of the 7 dummy chassis which mate onto the payload assembly.	0 D	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0
Dummy Chassis & Data Encoder	D04	30,340 E	Internal surface areas of the 7 dummy chassis, including all wiring, electrical components, circuit boards, etc.	7 (63) D	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	70
Dummy Chassis & Data Encoder	D05	819 E	(a) Total no. of rivets=1820 (b) Average surface area =0.45. (c)(a)x(b) = 819.	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0

CMIM STERILIZATION PROGRAM

DEFINITIONS OF ZONES AND COUPON QUANTITIES
(See explanatory notes on Page 1 of this Appendix)

Part	Zone	Surface Area ($In.^2$)	Description of Area	Quantity of coupons to be removed and zone classification at each estimation point.									Total Coupon Quantity
				1	2	3	4	5	6	7	8	9	
mmy assis Data coder	D06	56.	Handled areas on the front panel of the data encoder. 2x(7x4)=56 sq"	0 D	1 * A-1	1 A-2	1 A-3	2 A-4	2 A-5	1 (4) A-6	0 0	0 0	
mmy assis Data coder	D07	310.	Unhandled portion of the front panel of the data encoder.	1 D	0 C	4 C	0 C	3 C	0 C	2 C	0 0	0 0	10
mmy assis Data coder	D08	46.	Portion of the data encoder case which mates onto the payload assembly.	0 D	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0
mmy assis Data coder	D09	4791 [E]	Internal surface areas of the data encoder, including all wiring, electrical components, circuit boards etc.	2 (8) D	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	10
mmy assis Data coder	D10	117 [E]	(a) Total No. of rivets=260. (b) Average surface area= 0.45. (c) (a)x(b)= 117.	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0 M	

CMTM STERILIZATION PROGRAM

DEFINITIONS OF ZONES AND COUPON QUANTITIES
(See explanatory notes on Page 1 of this Appendix)

Part	Zone	Surface Area ($In.^2$)	Description of Area	Quantity of coupons to be removed and zone classification at each estimation point.									Total Coupon Quanti
				1	2	3	4	5	6	7	8	9	
Impact Limiter	I01	622.	Surface on top of Impact Limiter whose border is horizontal circle of radius=13.4"	1 D	0 B	1 (4) B	0 0	0 0	0 0	0 0	0 0	0 0	6
Impact Limiter	I02	1308.	Three surfaces containing lift hooks. These are bordered by the horizontal circles of radii, 13.4" & 22.5" and by arcs ± 30° of the centerline of hooks.	1 D	0 D	7 (22) * A-1	0 0	0 0	0 0	0 0	0 0	0 0	30
Impact Limiter	I03	1282.	Three surfaces on upper half of Impact Limiter bordered on top and bottom by circles of radii 13.4" & 22.5", respectively, and not included in zone I02.	1 D	0 C	3 (26) C	0 0	0 0	0 0	0 0	0 0	0 0	30
Impact Limiter	I04	2565.	Surface of Impact Limiter on bottom half of sphere whose borders are horizontal circles of radii 22.5" & 13.4". This surface is occluded by chassis.	0 D	0 D	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0
Impact Limiter	I05	622.	Surface on bottom of Impact Limiter whose border is a horizontal circle of radius 13.4".	0 D	0 D	0 I	0 I	0 0	0 0	0 0	0 0	0 0	0

IMPACT LIMITER

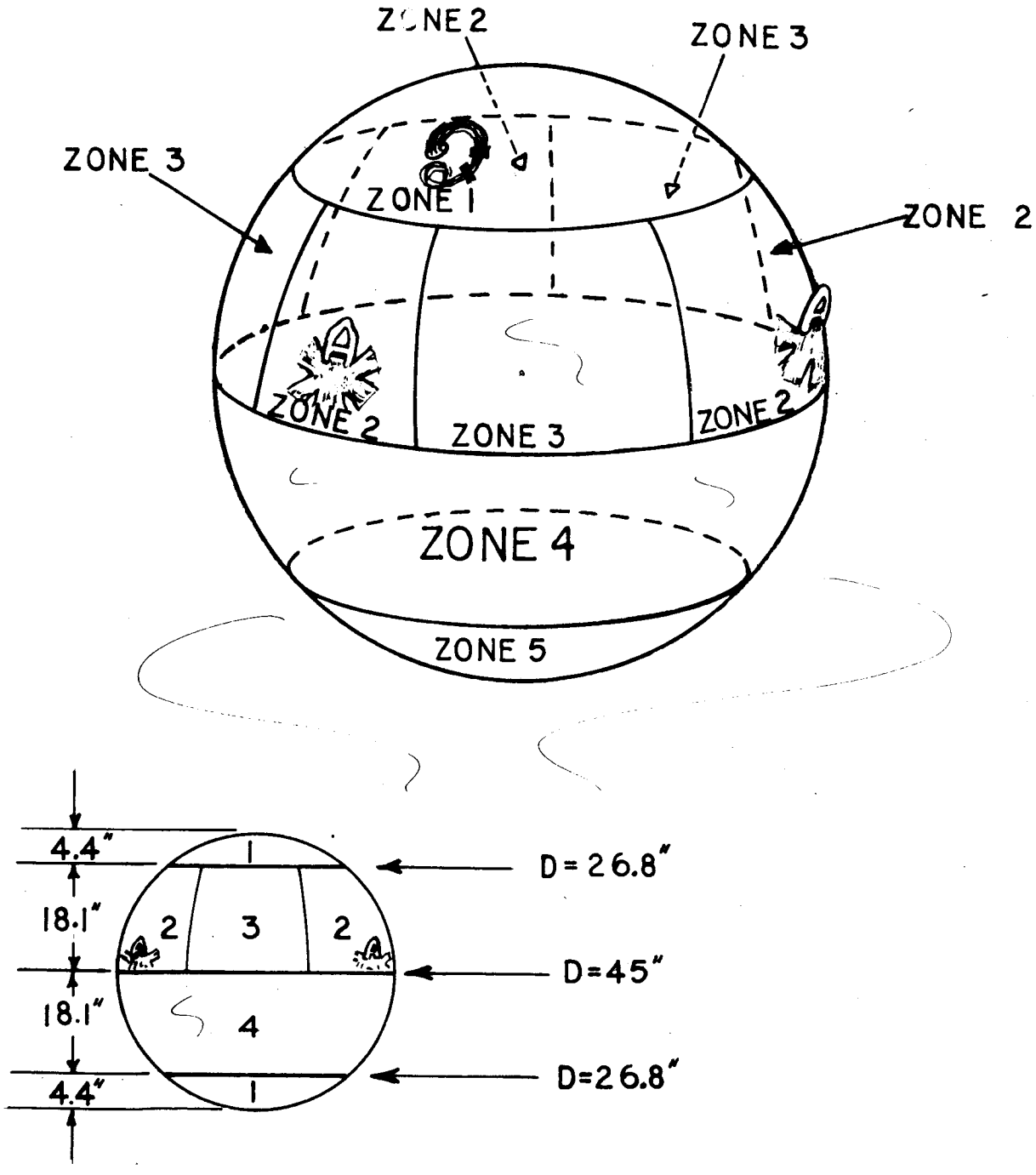


Figure 4-5 ZONE DEFINITION - IMPACT LIMITER

CMTM STERILIZATION PROGRAM

DEFINITIONS OF ZONES AND COUPON QUANTITIES
(See explanatory notes on Page 1 of this Appendix)

Part	Zone	Surface Area ($In.^2$)	Description of Area	Quantity of coupons to be removed and zone classification at each estimation point.									Total Coupo Quant
				1	2	3	4	5	6	7	8	9	
Deorbit Motor	M01	306.	Top of motor above clamp location, (This becomes occluded immediately after assembly). Plus mated surface.	1 (2) D	0 C	0 C	0 C	0 C	0 0	0 0	0 0	0 0	3
Deorbit Motor	M02	1253.	Side surface of motor beneath clamp location.	1 D	0 D	0 D	0 D	0 D	0 D	1 (4) D	0 0	0 0	6
Deorbit Motor	M03	1574.	Bottom of motor and internal shell area and inside tank.	0 D	0 D	0 D	0 D	0 D	0 D	1 (2) D	0 0	0 0	3
Deorbit Motor	M04	500. E.	Cabling. (Not including the connectors).	0 D	0 D	0 D	0 D	0 D	0 B	5 (5) B	0 0	0 0	10
Deorbit Motor	M05	25. E	Cabling Connectors.	0 D	0 D	0 D	0 D	0 D	0 B	1 (1) B	0 * 0	0 0	2

CMIM STERILIZATION PROGRAM

DEFINITIONS OF ZONES AND COUPON QUANTITIES
(See explanatory notes on Page 1 of this Appendix)

Part	Zone	Surface Area ($In.^2$)	Description of Area	Quantity of coupons to be removed and zone classification at each estimation point.									Total Coupon Quantity
				1	2	3	4	5	6	7	8	9	
otor lamp ssembly	001	56.0	Outside and edges.	0 D	0 D	0 D	0 D	0 D	0 * I	0 I	0 0	0 0	0
otor lamp ssembly	002	54.0	Inside (occluded).	0 D	0 D	0 D	0 D	0 D	0 0	0 0	0 0	0 0	0
otor lamp ssembly	003	2.0 E	Screws, etc.	0 I	0 I	0 I	0 I	0 I	0 * 0	0 0	0 0	0 0	0

DE-ORBIT MOTOR

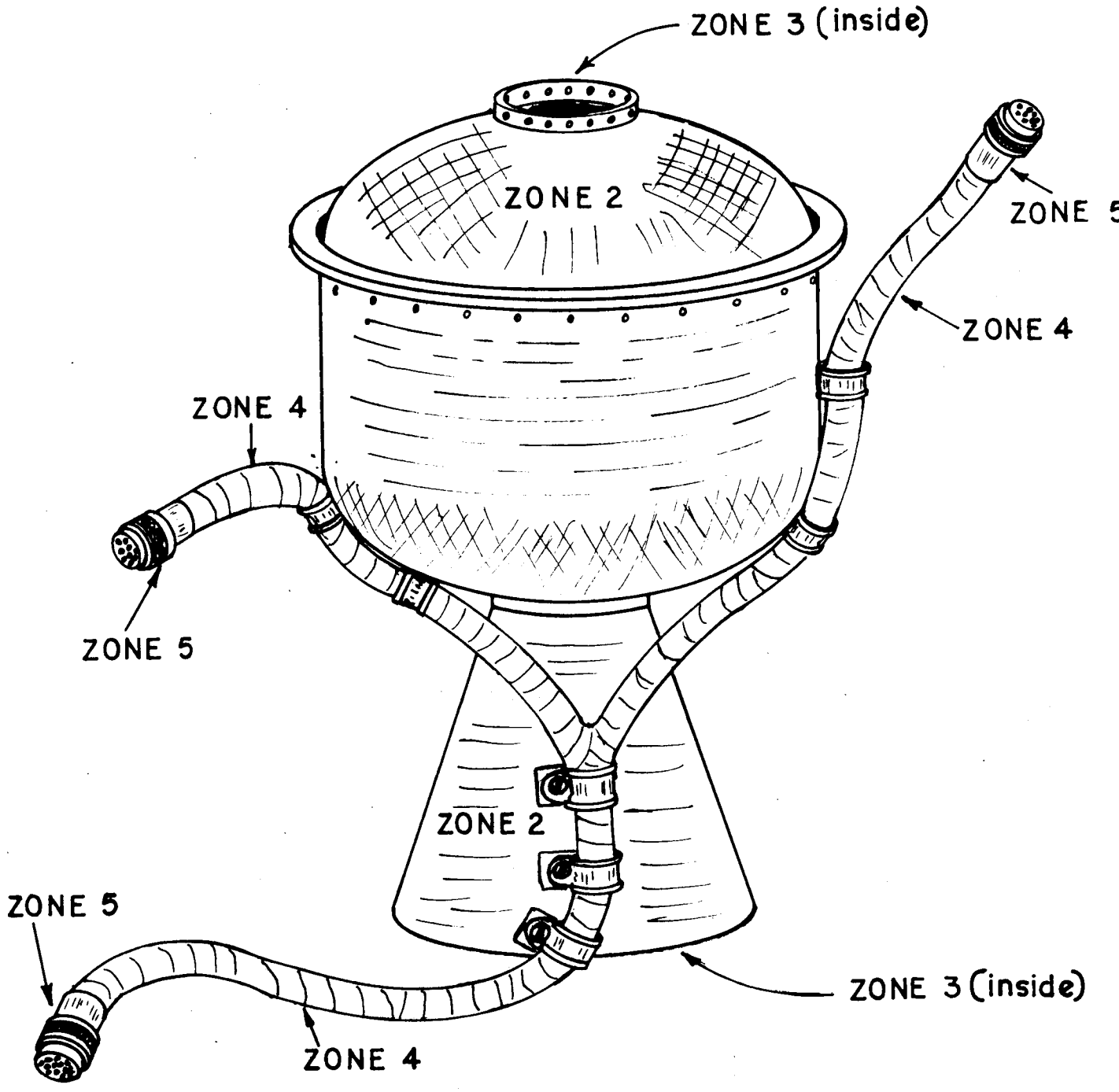


Figure 4-6 ZONE DEFINITION - DE-ORBIT MORTOR

CMTM STERILIZATION PROGRAM

DEFINITIONS OF ZONES AND COUPON QUANTITIES
(See explanatory notes on Page 1 of this Appendix)

Part	Zone	Surface Area ($In.^2$)	Description of Area	Quantity of coupons to be removed and zone classification at each estimation point.									Total Coupon Quantity
				1	2	3	4	5	6	7	8	9	
chute ster	P01	176.	Top surface.	0 D	0 B	0 B	0 B	0 I	0 I	0 I	0 0	0 0	0
chute ster	P02	240.	Bottom Surface	0 D	0 D	0 D	0 D	7 (11) A-1 *	0 0	0 0	0 0	0 0	18
chute ster	P03	760	Cylindrical Side surface (possibly a light contact area).	1 D	0 C	0 C	0 C	7 (8) B	0 I	0 I	0 0	0 0	16
chute ster	P04	21.	Top flange.	0 D	0 B	0 B	0 B	0 I	0 I	0 I	0 0	0 0	0
chute ster	P05	89.	Bottom flange	0 D	0 D	0 D	0 D	0 * M	0 M	0 M	0 M	0 M	0

CMTM STERILIZATION PROGRAM

DEFINITIONS OF ZONES AND COUPON QUANTITIES
(See explanatory notes on Page 1 of this Appendix)

Part	Zone	Surface Area ($In.^2$)	Description of Area	Quantity of coupons to be removed and zone classification at each estimation point.									Total Coupon Quan
				1	2	3	4	5	6	7	8	9	
Antenna Relay	R01	19.^{E}	Top Surface (Except portion mated to payload)	0 D	0 B	0 B	0 B	0 B	0 B	1 (2) B	0 0	0 0	3
Antenna Relay	R02	254.	Bottom Surface	0 D	0 D	0 D	0 D	0 D	0 D	3 (3)* A-1	0 0	0 0	6
Antenna Relay	R03	550	Cylindrical side wall surface.	1 D	0 D	0 D	0 D	0 D	0 D	4 (10) A-1*	0 0	0 0	15
Antenna Relay	R04	264.^{E}	Top surface mated to the payload assembly.	0 D	0 D	0 D	0 D	0 D	0 D	0 M*	0 M	0 M	0

CMTM STERILIZATION PROGRAM

DEFINITIONS OF ZONES AND COUPON QUANTITIES
(See explanatory notes on Page 1 of this Appendix)

Part	Zone	Surface Area ($In.^2$)	Description of Area	Quantity of coupons to be removed and zone classification at each estimation point.									Total Coupon Quantity
				1	2	3	4	5	6	7	8	9	
load embly	S01	366.	Portion of the columns which become mated when the chassis and the data encoder are mated.	3 (5) D	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0 M	8
load y.	S02	7022.	All the type C areas which remain exposed after the completion of the CMTM assembly. This includes the cylindrical side wall and bottom flange, the struts (inside and out), the side walls (both sides) in the mid-support section, the upper shelves (top sides) above the bays, the portions of the columns between bays which are not mated, and the exposed areas of all brackets.	2 D	0 C	7 C	0 C	6 C	0 C	6 (43) C	0 0	0 0	64
rload ;y.	S03	264. E	The bottom area directly under the bays which becomes mated by the assembly of the antenna relay.	0 D	0 D	1 D	0 D	1 D	0 D	0 M	0 M	0 M	2

CMIM STERILIZATION PROGRAM

DEFINITIONS OF ZONES AND COUPON QUANTITIES
(See explanatory notes on Page 1 of this Appendix)

Part	Zone	Surface Area ($In.^2$)	Description of Area	Quantity of coupons to be removed and zone classification at each estimation point.									Total Coupo Quant
				1	2	3	4	5	6	7	8	9	
Payload Assy.	S04	1236. E	The bottom area directly under the bays minus zone S03.	1 D	0 D	3 D	0 D	3 D	0 D	6 D	0 0	0 0	14
Payload Assy.	S05	1635.	The de-orbit motor mount surface area excluding those portions which are occluded by the parachute canister and the motor, i.e. the shelf and internal areas.	0 D	0 D	3 D	0 D	2 D	0 D	1 (10) D	0 0	0 0	16
Payload Assy.	S06	12.	ID of shelf which becomes occluded by the parachute canister. This surface is contacted during assembly of the data encoder to bay 8.	0 D	1 * A-1	0 A-2	2 (3) A-3	0 0	0 0	0 0	0 0	0 0	6
Payload Assy.	S07	128.	ID of motor mount which becomes occluded by the assembly of the motor. This is contacted during the assembly of the data encoder to bay 8.	0 D	1 * A-1	1 A-2	1 A-3	1 (4) A-4	0 0	0 0	0 0	0 0	8

CMTM STERILIZATION PROGRAM

DEFINITIONS OF ZONES AND COUPON QUANTITIES
(See explanatory notes on Page 1 of this Appendix)

Part	Zone	Surface Area ($In.^2$)	Description of Area	Quantity of coupons to be removed and zone classification at each estimation point.									Total Coupon Quantity
				1	2	3	4	5	6	7	8	9	
'ayload ssy.	S08	5798.	The areas inside the bays which become occluded by the assembly of the dummy chassis & data encoder.	10 (38) D	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	48
ayload ssy.	S09	14.	Bottom surface of the motor mount, which becomes entirely mated by the assembly of the motor.	0 D	0 D	0 D	0 D	0 D	0 M	0 M	0 M	0 M	0
ayload ssy.	S10	7180.	All the internal portions which are inaccessible and become occluded by the mating of the parachute canister.	0 D	0 I	0 I	0 I	0 O	0 O	0 O	0 O	0 O	0
ayload ssy.	S11	922.	The top flange which mates to the aeroshell and becomes mated after the aeroshell assembly.	0 D	0 B	2 (4) B	0 M	0 M	0 M	0 M	0 M	0 M	6
ayload ssy.	S12	2610	Portion which mates to the Impact Limiter, including the bowl surface and the rubber receivers.	3 (3) D	0 C	0 0	0 0	0 0	0 0	0 0	0 0	0 0	6

CMIM STERILIZATION PROGRAM

DEFINITIONS OF ZONES AND COUPON QUANTITIES
(See explanatory notes on Page 1 of this Appendix)

Part	Zone	Surface Area ($In.^2$)	Description of Area	Quantity of coupons to be removed and zone classification at each estimation point.									Tota Coup Quar
				1	2	3	4	5	6	7	8	9	
Payload Assy	S13	1500^E	All permanently mated surfaces.	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0
Payload Assy	S14	900^E	(a) Number of rivets=2000. (b) Average area=0.45. (a)x(b)=900^E.	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0 M	0

CMTM STERILIZATION PROGRAM

DEFINITIONS OF ZONES AND COUPON QUANTITIES
(See explanatory notes on Page 1 of this Appendix)

Part	Zone	Surface Area ($In.^2$)	Description of Area	Quantity of coupons to be removed and zone classification at each estimation point.									Total Coupon Quantity
				1	2	3	4	5	6	7	8	9	
Umbilical	U01	255.	Connector plate.	2 D	0 D	2 D	0 D	0 D	0 D	0 D	4 (13) *A-1	0 0	21
Umbilical	U02	116[E]	Cabling at the connector plate area (i.e. the 5 connectors).	0 D	0 B	1 B	0 B	0 B	0 B	0 B	1 (4) *A-1	0 0	6
Umbilical	U03	795[E].	Cabling.	1 D	0 B	3 (5) B	0 B	0 B	0 B	0 B	0 B	0 0	9
Umbilical	U04	20[E]	Connector at Data Encoder.	0 D	0 *I	0 I	0 I	0 0	0 0	0 0	0 0	0 0	0
Total All Subassemblies	75	249,346.	CMTM and Canister. (Including only the inside of the Canister).	60	7	108	19	109	16	106	7	68	500
			Total dummy coupons:	121	0	64	3	23	0	411	18	250	890
			Total coupons:	181	7	172	22	132	16	517	25	318	1390

APPENDIX C

COUPON REMOVAL SCHEDULE

July, 1967

CMTM STERILIZATION PROGRAM

SADL ASSEMBLY OPERATION COUPON REMOVAL SCHEDULE

ESTIMATION POINT 1. DATE:_____, 19_____. TIME:_____.

(Section 1.0, Oper. 5)

To Be Removed For Assay:

A01-17	A10-45	D04-53	P03-13	S08-23
AX1-35	A10-55	D04-41	R03-03	S08-29
AX1-55	A10-57	D04-59	S01-01	S08-33
AX1-71	A11-13	D04-64	S01-05	S08-39
AX1-95	A11-43	D07-01	S01-08	S08-45
A02-35	A11-61	D09-02	S02-33	S08-47
A02-99	A13-01	D09-07	S02-55	S12-01
AX2-07	D02-53	I01-03	S04-11	S12-03
A03-17	D02-55	I02-19	S08-01	S12-06
A04-29	D04-17	I03-29	S08-05	U01-01
A07-03	D04-21	M01-01	S08-10	U01-07
A10-15	D04-33	M02-01	S08-18	U03-05

All Coupons Are To Be Removed From The Following Zones:

A07	(2)
D04	(63)
D09	(8)
M01	(2)
S01	(5)
S08	(38)
S12	(3)

ESTIMATION POINT 2.

(Section 1.0 Oper. 90) DATE:_____,19_____. TIME:_____.

To Be Removed For Assay:

D01-45
D01-50
D01-75
D01-77
D06-03
S06-05

ESTIMATION POINT 3. Date: _____, 19____. TIME:_____
(Sec. 2.0, Oper. 50)

To Be Removed For Assay:

A01-10	A02-77	B02-02	D02-67	S02-49
A01-12	A02-92	B02-03	D02-69	S02-54
A01-31	AX2-04	B02-04	D02-70	S02-56
A01-45	A03-02	D01-11	D06-10	
A01-63	A04-04	D01-20	D07-04	S02-60
A01-80	A05-28	D01-23	D07-08	S03-02
A01-88	A06-24	D01-32	D07-09	S04-08
A01-95	A09-01	D01-39	D07-10	S04-09
AX1-11	A10-51	D02-04	I01-05	S04-10
AX1-18	A10-52	D02-05	I02-04	S05-04
AX1-24	A10-56	D02-08	I02-07	S05-05
AX1-40	A10-84	D02-28	I02-10	S05-08
AX1-49	A10-88	D02-41	I02-13	S07-02
AX1-53	A11-03	D02-43	I02-14	S11-04
AX1-73	A11-10	D02-46	I02-25	S11-06
AX1-99	A11-22	D02-49	I02-27	U01-05
AY1-08	A11-31	D02-52	I03-02	U01-12
A02-16	A11-36	D02-57	I03-07	U02-02
A02-28	A12-02	D02-61	I03-23	U03-01
A02-42	A13-06	D02-63	S02-12	U03-04
A02-53	B01-03	D02-65	S02-20	U03-09
A02-74	B01-10	D02-66	S02-38	

ALL COUPONS ARE TO BE REMOVED FROM THE FOLLOWING ZONES:

A09 (2)
B02 (1)
I01 (4)
I02 (22)
I03 (26)
S11 (4)
U03 (5)

ESTIMATION POINT 4
(Sec. 3.0, Oper. 90) Date: _____, 19_____. TIME:_____

A03-11	A05-05	B01-07	D01-36	D06-11
A03-15	A05-26	B01-18	D01-71	S06-01
A03-27	A06-26	B03-02	D01-82	S06-04
A04-11	A06-29			S07-04
A04-17				

ALL COUPONS ARE TO BE REMOVED FROM ZONE S06 (3 COUPONS).

ESTIMATION POINT 5.
(Sec. 4.0, Oper. 80) Date:_____, 19_____. TIME:_____

To Be Removed For Assay:

A01-05	A02-76	A11-06	D02-10	P02-12
A01-07	A02-89	A11-07	D02-13	P02-15
A01-11	A02-97	A11-08	D02-16	P02-18
A01-23	AX2-06	A11-17	D02-18	P03-02
A01-25	A03-12	A11-37	D02-19	P03-05
A01-36	A03-25	A11-48	D02-24	P03-06
A01-43	A04-25	A11-71	D02-27	P03-08
A01-49	A04-28	A11-82	D02-30	P03-11
A01-93	A05-07	A11-88	D02-32	P03-14
A01-97	A05-11	A11-89	D02-34	P03-15
AX1-09	A06-09	A11-90	D02-38	S02-10
AX1-31	A06-15	A12-04	D02-40	S02-32
AX1-43	A06-25	A13-03	D02-68	S02-37
AX1-57	A10-03	A16-03	D06-01	S02-43
AX1-61	A10-08	B01-12	D06-07	S02-47
AX1-81	A10-26	B01-20	D07-02	S02-64
AY1-07	A10-35	C01-03	D07-06	S03-01
A02-26	A10-41	D01-08	P02-03	S04-01
A02-55	A10-44	D01-13	P02-08	S04-03
A02-61	A10-59	D01-16	P02-10	S04-04
A02-67	A10-62	D01-67	P02-11	S05-06
A02-72				S05-09
				S07-05

ALL COUPONS ARE TO BE REMOVED FROM THE FOLLOWING ZONES:

P02	(11)
P03	(8)
S07	(4)

ESTIMATION POINT 6
(Sec. 5.0, Oper. 60) Date:_____, 19_____. TIME:_____

To Be Removed For Assay:

A03-04	A06-22	B03-01	D01-59
A04-19	A06-27	D01-15	D01-64
A04-23	B01-09	D01-26	D06-05
A05-04	B01-19	D01-46	D06-08

CMTM STERILIZATION PROGRAM July 1967

SADL ASSEMBLY OPERATION COUPON REMOVAL SCHEDULE

ESTIMATION POINT 7
(Sec. 6.0 Oper. 30) Date:_____, 19_____. TIME:_____

A01-02	A02-27	A11-16	D01-62	M03-03
A01-27	A02-63	A11-18	D02-02	M04-01
A01-29	A02-73	A11-49	D02-06	M04-03
A01-32	A02-90	A11-52	D02-09	M04-05
A01-51	A03-03	A11-57	D02-14	M04-07
A01-62	A03-30	A11-63	D02-15	M04-09
A01-75	A04-07	A11-70	D02-22	M05-01
A01-87	A04-16	A11-76	D02-25	R01-02
A01-98	A05-17	A11-79	D02-29	
AX1-25	A05-18	A11-86	D02-31	R02-01
Ax1-26	A06-23	A12-05	D02-37	R02-02
AX1-56	A10-01	A12-08	D02-42	R02-06
AX1-75	A10-21	A13-02	D02-50	Ro3-04
AX1-87	A10-22	A16-09	D02-54	R03-05
AX1-96	A10-42	B01-06	D02-60	R03-08
AY1-04	A10-65	D01-02	D02-62	R03-15
A02-02	A10-69	D01-03	D06-09	S02-15
A02-05	A10-71	D01-30	D07-03	S02-30
A02-13	A10-74	D01-42	D07-05	S02-39
A02-20	A10-79	D01-61	M02-04	S02-48
A02-23	A10-80			S02-51
	A11-02			S02-63
				S04-14
				S05-13

ALL COUPONS ARE TO BE REMOVED FROM THE FOLLOWING ZONES:

A03-	(20)	M02	(4)
A04	(22)	M03	(2)
A05	(22)	M04	(5)
A06	(21)	M05	(1)
A10	(63)	R01	(2)
A11	(60)	R02	(3)
A12	(6)	S02	(43)
A13	(8)	S04	(6)
A16	(8)	S05	(10)
B01	(11)	R03-	(10)
D01	(57)		
D02	(23)		
D06	(4)		

CMTM STERILIZATION PROGRAM July 1967

SADL ASSEMBLY OPERATION COUPON REMOVAL SCHEDULE

ESTIMATION POINT 8
(Sec. 8.0, Oper. 20) Date: _____, 19_____. TIME:_____

To Be Removed For Assay:

C01-01	U01-03	U01-14
C01-04	U01-04	U01-18
		U02-01

ALL COUPONS ARE TO BE REMOVED FROM THE FOLLOWING ZONES:

U01	(13)
U02	(4)
C01	(1)

ESTIMATION POINT 9.
(Sec. 9.0, Oper. 10) Date: _____, 19_____. TIME:_____

To Be Removed For Assay:

A01-09	AX1-28	A02-58	C02-24	C05-06
A01-26	AX1-32	A02-59	C04-06	C05-10
A01-26	AX1-37	A02-80	C04-07	C05-11
A01-35	AX1-69	A02-96	C04-10	C05-13
A01-41	AX1-78	C02-02	C04-12	C05-18
A01-55	AX1-85	C02-03	C04-03	C05-21
A01-57	AX1-92	C02-04	C04-15	C05-24
A01-58	AY1-01	C02-06	C04-18	C05-28
A01-59	AY1-05	C02-09	C04-22	
A01-61	A02-08	C02-10	C04-25	
A01-72	A02-09	C02-11	C04-27	
A01-90	A02-10	C02-12	C04-29	
AX1-14	A02-12	C02-18	C04-30	
AX1-19	A02-41	C02-19	C05-01	
AX1-20	A02-54	C02-23	C05-04	

ALL COUPONS ARE TO BE REMOVED FROM THE FOLLOWING ZONES:

A01, AX1, AY1	(131)
A02, AX2	(69)
C02	(12)
C04	(18)
C05	(20)

APPENDIX D

POST QUARANTINE COUPON REMOVAL SCHEDULE

CMTM STERILIZATION PROGRAM July 1967

POST QUARANTINE COUPON REMOVAL SCHEDULE

Date:_____, 19_____. TIME:_____

AFTER THE QUARANTINE PERIOD, THE FOLLOWING COUPONS ARE TO BE REMOVED FOR ASSAY:

A01-03	A02-29	A11-01	D01-63	M04-02
A01-28	A02-64	A11-15	D02-01	M04-04
A01-30	A02-75	A11-19	D02-03	M04-06
A01-33	A02-91	A11-50	D02-07	M04-08
A01-52	A03-05	A11-53	D02-11	M04-10
A01-60	A03-29	A11-58	D02-12	M05-02
A01-76	A04-08	A11-64	D02-17	R01-03
A01-86	A04-15	A11-69	D02-20	R02-03
A01-99	A05-16	A11-77	D02-21	R02-04
AX1-23	A05-19	A11-80	D02-23	R02-05
AX1-27	A06-21	A11-87	D02-26	R03-02
AX1-58	A10-02	A12-06	D02-36	R03-06
AX1-76	A10-20	A12-07	D02-45	R03-09
AX1-88	A10-23	A13-04	D02-47	R03-14
AX1-97	A10-43	A16-10	D02-51	S02-16
AY1-03	A10-66	B01-05	D02-56	S02-31
A02-03	A10-70	D01-01	D02-58	S02-40
A02-06	A10-72	D01-04	D02-64	S02-46
A02-14	A10-75	D01-31	D06-12	S02-50
A02-21	A10-78	D01-43	M02-05	S02-62
A02-24	A10-81	D01-60	M03-02	S04-13
				S05-14

APPENDIX E

DISPOSITION OF COUPONS

ON THE CMTM SURFACES

CMTM STERILIZATION PROGRAM

DISPOSITION OF COUPONS

Page 1 of 7

CODE: 1 = To be removed during assembly Estimation Point 1, and assayed.
d = Dummy coupon, to be removed but not assayed.
Qd = To be removed after the quarantine period, and assayed. To be a dummy coupon if there is no quarantine period.

A01-01	d	A01-29	7	A01-57	9	A01-85	d	AX1-13	d	AX1-41	d	AX1-69	9	AX1-97	Qd
02	7	30	Qd	58	9	86	Qd	14	9	42	d	70	d	98	d
03	Qd	31	3	59	9	87	7	15	d	43	5	71	1	99	3
04	d	32	7	60	Qd	88	3	16	d	44	d	72	d	AY1-00	d
05	5	33	Qd	61	9	89	d	17	d	45	d	73	3	01	9
06	d	34	d	62	7	90	9	18	3	46	d	74	d	02	d
07	5	35	9	63	3	91	d	19	9	47	d	75	7	03	Qd
08	d	36	5	64	d	92	d	20	9	48	d	76	Qd	04	7
09	9	37	d	65	d	93	5	21	d	49	3	77	d	05	9
10	3	38	d	66	d	94	d	22	d	50	d	78	9	06	d
11	5	39	d	67	d	95	3	23	Qd	51	d	79	d	07	5
12	3	40	d	68	d	96	d	24	3	52	d	80	d	08	3
13	d	41	9	69	d	97	5	25	7	53	3	81	5	09	d
14	d	42	d	70	d	98	7	26	7	54	d	82	d	10	d
15	d	43	5	71	d	99	Qd	27	Qd	55	1	83	d	A02-01	d
16	d	44	d	72	9	AX1-00	d	28	9	56	7	84	d	02	7
17	1	45	3	73	d	01	d	29	d	57	5	85	9	03	Qd
18	d	46	d	74	d	02	d	30	d	58	Qd	86	d	04	d
19	d	47	d	75	7	03	d	31	5	59	d	87	7	05	7
20	9	48	d	76	Qd	04	d	32	9	60	d	88	Qd	06	Qd
21	d	49	5	77	d	05	d	33	d	61	5	89	d	07	d
22	d	50	d	78	d	06	d	34	d	62	d	90	d	08	9
23	5	51	7	79	d	07	d	35	1	63	d	91	d	09	9
24	d	52	Qd	80	3	08	d	36	d	64	d	92	9	10	9
25	5	53	d	81	d	09	5	37	9	65	d	93	d	11	d
26	9	54	d	82	d	10	d	38	d	66	d	94	d	12	9
27	7	55	9	83	d	11	3	39	d	67	d	95	1	13	7
28	Qd	56	d	84	d	12	d	40	3	68	d	96	7	14	Qd

DISPOSITION OF COUPONS

Page 2 of 7

CODE: 1 = To be removed during Estimation Point 1, and assayed.
d = Dummy coupon, to be removed but not assayed.
Qd = To be removed after the quarantine period, and assayed. To be a dummy coupon if there is no quarantine period.

A02-15	A02-43	A02-71	A02-99	A03-19	A04-17	A05-13	A06-11
16 3	44 d	72 5	AX2-00 d	20 d	18 d	14 d	12
17 d	45 d	73 7	01 d	21 d	19 6	15 d	13
18 d	46 d	74 3	02 d	22 d	20 d	16 Qd	14
19 d	47 d	75 Qd	03 d	23 d	21 d	17 7	15
20 7	48 d	76 5	04 3	24 d	22 d	18 7	16
21 Qd	49 d	77 3	05 d	25 5	23 6	19 Qd	17
22 d	50 d	78 d	06 5	26 d	24 d	20 d	18
23 7	51 d	79 d	07 1	27 4	25 5	21 d	19
24 Qd	52 d	80 9	08 d	28 d	26 d	22 d	20
25 d	53 3	81 d	A03-01 d	29 Qd	27 d	23 d	21
26 5	54 9	82 d	02 3	30 7	28 5	24 d	22
27 7	55 5	83 d	03 7	A04- 01 d	29 1	25 d	23
28 3	56 d	84 d	04 6	02 d	30 d	26 4	24
29 Qd	57 d	85 d	05 Qd	03 d	31 d	27 d	25
30 d	58 9	86 d	06 d	04 3	32 d	28 3	26
31 d	59 9	87 d	07 d	05 d	A05-01 d	29 d	27
32 d	60 d	88 d	08 d	06 d	02 d	30 d	28
33 d	61 5	89 5	09 d	07 7	03 d	A06-01 d	29
34 d	62 d	90 7	10 d	08 Qd	04 6	02 d	30
35 1	63 7	91 Qd	11 4	09 d	05 4	03 d	A07-01
36 d	64 Qd	92 3	12 5	10 d	06 d	04 d	02
37 d	65 d	93 d	13 d	11 4	07 5	05 d	03
38 d	66 d	94 d	14 d	12 d	08 d	06 d	A09-01
39 d	67 5	95 d	15 4	13 d	09 d	07 d	02
40 d	68 d	96 9	16 d	14 d	10 d	08 d	03
41 9	69 d	97 5	17 1	15 Qd	11 5	09 5	A10-01
42 3	70 d	98 d	18 d	16 7	12 d	10 d	02

CMTM STERILIZATION PROGRAM

DISPOSITION OF COUPONS

CODE: .1 = To be removed during Estimation Point 1, and assayed.
d = Dummy coupon, to be removed but not assayed.
Qd = To be removed, after the quarantine period and assayed. To be a dummy coupon if there is no quarantine period.

A10-03 5	A10-31 d	A10-59 5	A10-87 d	A11-25 d	A11-53 Qd	A11-81 d	A13-09 d
04 d	32 d	60 d	88 3	26 d	54 d	82 5	10 d
05 d	33 d	61 d	89 d	27 d	55 d	83 d	11 d
06 d	34 d	62 5	90 d	28 d	56 d	84 d	12 d
07 d	35 5	63 d	A11-01 Qd	29 d	57 7	85 d	A16-01 d
08 5	36 d	64 d	02 7	30 d	58 Qd	86 7	02 d
09 d	37 d	65 7	03 3	31 3	59 d	87 Qd	03 5
10 d	38 d	66 Qd	04 d	32 d	60 d	88 5	04 d
11 d	39 d	67 d	05 d	33 d	61 1	89 5	05 d
12 d	40 d	68 d	06 5	34 d	62 d	90 5	06 d
13 d	41 5	69 7	07 5	35 d	63 7	A12-01 d	07 d
14 d	42 7	70 Qd	08 5	36 3	64 Qd	02 3	08 d
15 1	43 Qd	71 7	09 d	37 5	65 d	03 d	09 7
16 d	44 5	72 Qd	10 3	38 d	66 d	04 5	10 Qd
17 d	45 1	73 d	11 d	39 d	67 d	05 7	B01-01 d
18 d	46 d	74 7	12 d	40 d	68 d	06 Qd	02 d
19 d	47 d	75 Qd	13 1	41 d	69 Qd	07 Qd	03 3
20 Qd	48 d	76 d	14 d	42 d	70 7	08 7	04 d
21 7	49 d	77 d	15 Qd	43 1	71 5	09 d	05 Qd
22 7	50 d	78 Qd	16 7	44 d	72 d	10 d	06 7
23 Qd	51 3	79 7	17 5	45 d	73 d	A13-01 1	07 4
24 d	52 3	80 7	18 7	46 d	74 d	02 7	08 d
25 d	53 d	81 Qd	19 Qd	47 d	75 d	03 5	09 6
26 5	54 d	82 d	20 d	48 5	76 7	04 Qd	10 3
27 d	55 1	83 d	21 d	49 7	77 Qd	05 d	11 d
28 d	56 3	84 3	22 3	50 Qd	78 d	06 3	12 5
29 d	57 1	85 d	23 d	51 d	79 7	07 d	13 d
30 d	58 d	86 d	24 d	52 7	80 Qd	08 d	14 d

DISPOSITION OF COUPONS

CODE
1 = To be removed during Estimation Point 1, and assayed.
d = Dummy coupon, to be removed but not assayed
Qd = To be removed after the quarantine period, and assayed. To be a dummy coupon if there is no quarantine period.

01-15	d	C02-13	d	C04-17	d	C05-15	d	D01-13	5	D01-41	d	D01-69	d	D02-13	
16	d	14	d	18	9	16	d	14	d	42	7	70	d	14	
17	d	15	d	19	d	17	d	15	6	43	Qd	71	4	15	
18	4	16	d	20	d	18	9	16	5	44	d	72	d	16	
19	6	17	d	21	d	19	d	17	d	45	2	73	d	17	
20	5	18	9	22	9	20	d	18	d	46	6	74	d	18	
B02-01	d	19	9	23	d	21	9	19	d	47	d	75	2	19	
02	3	20	d	24	d	22	d	20	3	48	d	76	d	20	
03	3	21	d	25	9	23	d	21	d	49	d	77	2	21	
04	3	22	d	26	d	24	9	22	d	50	2	78	d	22	
B03-01	6	23	9	27	9	25	d	23	3	51	d	79	d	23	
02	4	24	9	28	d	26	d	24	d	52	d	80	d	24	
C01-01	8	C04-01	d	29	9	27	d	25	d	53	d	81	d	25	
02	7	02	d	30	9	28	9	26	6	54	d	82	4	26	
03	5	03	9	C05-01	9	29	d	27	d	55	d	83	d	27	
04	8	04	d	02	d	30	d	28	d	56	d	84	d	28	
C02-01	d	05	d	03	d	D01-01	Qd	29	d	57	d	D02-01	Qd	29	
02	9	06	9	04	9	02	7	30	7	58	d	02	7	30	
03	9	07	9	05	d	03	7	31	Qd	59	6	03	Qd	31	
04	9	08	d	06	9	04	Qd	32	3	60	Qd	04	3	32	
05	d	09	d	07	d	05	d	33	d	61	7	05	3	33	
06	9	10	9	08	d	06	d	34	d	62	7	06	7	34	
07	d	11	d	09	d	07	d	35	d	63	Qd	07	Qd	35	
08	d	12	9	10	9	08	5	36	4	64	6	08	3	36	
09	9	13	d	11	9	09	d	37	d	65	d	09	7	37	
10	9	14	d	12	d	10	d	38	d	66	d	10	5	38	
11	9	15	9	13	9	11	3	39	3	67	5	11	Qd	39	
12	9	16	d	14	d	12	d	40	d	68	d	12	Qd	40	

DISPOSITION OF COUPONS

CODE: .1 = To be removed during Estimation Point 1, and assayed.
d = Dummy coupon, to be removed but not assayed.
Qd = To be removed, after the quarantine period, and assayed. To be a dummy coupon if there is no quarantine period.

D02-41	D02-69	D04-27	D04-55	D07-01	I02-03	I03-01	I03-29
42	70	28	56	02	04	02	30
43	D04-01	29	57	03	05	03	M01-01
44	02	30	58	04	06	04	02
45	03	31	59	05	07	05	03
46	04	32	60	06	08	06	M02-01
47	05	33	61	07	09	07	02
48	06	34	62	08	10	08	03
49	07	35	63	09	11	09	04
50	08	36	64	10	12	10	05
51	09	37	65	D09-01	13	11	06
52	10	38	66	02	14	12	M03-01
53	11	39	67	03	15	13	02
54	12	40	68	04	16	14	03
55	13	41	69	05	17	15	M04-01
56	14	42	70	06	18	16	02
57	15	43	D06-01	07	19	17	03
58	16	44	02	08	20	18	04
59	17	45	03	09	21	19	05
60	18	46	04	10	22	20	06
61	19	47	05	I01-01	23	21	07
62	20	48	06	02	24	22	08
63	21	49	07	03	25	23	09
64	22	50	08	04	26	24	10
65	23	51	09	05	27	25	M05-01
66	24	52	10	06	28	26	02
67	25	53	11	I02-01	29	27	
68	26	54	12	02	30	28	

CMTM STERILIZATION PROGRAM

DISPOSITION OF COUPONS

Page 6 Of 7

CODE: 3.1 = To be removed during Estimation Point 1, and assayed.
d = Dummy coupon, to be removed but not assayed.
Qd = To be removed, after the quarantine period and assayed. To be a dummy coupon if there is no quarantine period.

P02-01 d	P03-09 d	R03-12 d	S02-17 d	S02-45 d	S04-07 d	S06-05 2	S08-19	
02 d	10 d	13 d	18 d	46 Qd	08 3	06 d	20	
03 5	11 5	14 Qd	19 d	47 5	09 3	S07-01 d	21	
04 d	12 d	15 7	20 3	48 7	10 3	02 3	22	
05 d	13 1	S01-01 1	21 d	49 3	11 1	03 4	23	
06 d	14 5	02 d	22 d	50 Qd	12 d	04 d	24	
07 d	15 5	03 d	23 d	51 7	13 Qd	05 5	25	
08 5	16 d	04 d	24 d	52 d	14 7	06 d	26	
09 d	R01-01 d	05 1	25 d	53 d	S05-01 d	07 2	27	
10 5	02 7	06 d	26 d	54 3	02 d	08 d	28	
11 5	03 Qd	07 d	27 d	55 1	03 d	S08-01 1	29	
12 5	R02-01 7	08 1	28 d	56 3	04 3	02 d	30	
13 d	02 7	S02-01 d	29 d	57 d	05 3	03 d	31	
14 d	03 Qd	02 d	30 7	58 d	06 5	04 d	32	
15 5	04 Qd	03 d	31 Qd	59 d	07 d	05 1	33	
16 d	05 Qd	04 d	32 5	60 3	08 3	06 d	34	
17 d	06 7	05 d	33 1	61 d	09 5	07 d	35	
18 5	R03-01 d	06 d	34 d	62 Qd	10 d	08 d	36	
P03-01 d	02 Qd	07 d	35 d	63 7	11 d	09 d	37	
02 5	03 1	08 d	36 d	64 5	12 d	10 1	38	
03 d	04 7	09 d	37 5	S03-01 5	13 7	11 d	39	
04 d	05 7	10 5	38 3	02 3	14 Qd	12 d	40	
05 5	06 Qd	11 d	39 7	S04-01 5	15 d	13 d	41	
06 5	07 d	12 3	40 Qd	02 d	16 d	14 d	42	
07 d	08 7	13 d	41 d	03 5	S06-01 4	15 d	43	
08 5	09 Qd	14 d	42 d	04 5	02 d	16 d	44	
	10 d	15 7	43 5	05 d	03 d	17 d	45	
	11 d	16 Qd	44 d	06 d	04 4	18 1	46	

CMTM STERILIZATION PROGRAM

DISPOSITION OF COUPONS

Page 7 Of 7

CODE: .1 = To be removed during Estimation Point 1, and assayed.
d = Dummy coupon, to be removed but not assayed.
Qd = To be removed, after the quarantine period and assayed. To be a dummy coupon if there is no quarantine period.

S08-47	1	U01-15	d				
48	d	16	d				
S11-01	d	17	d				
02	d	18	8				
03	d	19	d				
04	3	20	d				
05	d	21	d				
06	3	U02-01	8				
S12-01	1	02	3				
02	d	03	d				
03	1	04	d				
04	d	05	d				
05	d	06	d				
06	1	U03-01	3				
U01-01	1	02	d				
02	d	03	d				
03	8	04	3				
04	8	05	1				
05	3	06	d				
06	d	07	d				
07	1	08	d				
08	d	09	3				
09	d						
10	d						
11	d						
12	3						
13	d						
14	8						

APPENDIX F

SUGGESTED DATA FORMS

FORM #_____ SAMPLE HEAT SHOCKED? YES☐ NO☐
AEROBIC☐ ANAEROBIC☐

ASSAY OF PERSONNEL

CMTM STERILIZATION PROGRAM

PAGE__ of__

SAMPLE ZONE_____ SAMPLE METHOD_____ PERSON SAMPLED_____ EXPERIMENTER_____ DATE_____

PERSONNEL PRESENT:_____ TYPES OF ORGANISMS REPRESENTED**_____ TIME_____

PREVIOUS OPERATION_____ AREA OF SAMPLE_____ IN.² SUPERVISOR_____ MEDIUM_____ OPERATION_____

REPLICATE #	-1A-				-2A-				-3A-				-1B-				-2B-				-3B-				-1C-				-2C-				-3C-			
INCUBATION (HR.)	24	48	72	*	24	48	72	*	24	48	72	*	24	48	72	*	24	48	72	*	24	48	72	*												
AM'T. of INOCUL.																																				
AVERAGE COUNT▲																																				
REPORTED COUNT▲																																				
NO. OF COLONY TYPES																																				
INCUBATION TEMPERATURE_____ °C													INCUBATION TEMP._____ °C												INCUBATION TEMP._____ °C											
ADDITIONAL TESTS RUN ON DIFFERENT COLONY TYPES					ADDITIONAL TESTS				ADDITIONAL TESTS				ADDITIONAL TESTS				ADDITIONAL TESTS				ADDITIONAL TESTS				ADDITIONAL TESTS				ADDITIONAL TESTS				ADDITIONAL TESTS			
NAME OF TEST	RESULTS ‡				RESULTS ‡				RESULTS ‡				RESULTS ‡				RESULTS ‡				RESULTS ‡				RESULTS ‡				RESULTS ‡				RESULTS ‡			
1																																				
2																																				
3																																				

NOTES AND OBSERVATIONS

** = VEGETATIVE AEROBES, VEG. ANAEROBES, AEROBIC SPORES, ANAEROBIC SPORES, COLIFORMS, ACTINOMYCES (AER.), FUNGI (AER.)
* = OTHER ‡ REPORT AS (+), (−), G (FOR GAS), A (FOR ACID)
▲ COUNTS REPORTED PER SQUARE INCH OF AREA SAMPLED

TABLE 4-5

FOLDOUT FRAME 1

FOLDOUT FRAME 2

FORM# ----

CMTM STERILIZATION PROGRAM ASSAY OF ENVIRONMENT TABLE 4-6

PAGE ____ OF ____

FACILITY ____________ . BUILDING ________ . ROOM ______ . LOCATION ________ . AIR TEMP ___ °C. RH ___ %. AIR VELOC. (↑) ___ , (↓) ___ , (N) ___ , (S) ___ , (W) ___ , (E) ___ .

EXPERIMENTOR ____________ . SUPERVISOR ____________ . START: DATE ______ 19__ , TIME ____ AM ___ PM. } SAMPLE TAKEN. DATE OF ASSAY ______ 19 ___

LIST NAMES OF PERSONS PRESENT ON REVERSE SIDE. FINISH: DATE ______ 19__ , TIME ____ AM ___ PM. }

TOTAL NO. OF PERSONS PRESENT ___ : ___ ASSEMBLERS (__S, __G), ___ FACILITY (__S, __G), ___ QA (__S, __G), ___ BACT. (__S, __G), ___ OTHERS (__S, __G). [S = In street clothes, G = Gowned]

ZONE ____________ TYPE OF AREA _____ * { AREA ____________ Ft². { VOLUME (IF AIR ASSAY) ______ Ft³. ACTIVITY * : ___ ___ ___ ___ ___ ___ FROM (DATE, TIME): ___ , ___ ___ , ___ ___ , ___ ___ , ___ ___ , ___ ___ , ___ TO (DATE, TIME): ___ , ___ ___ , ___ ___ , ___ ___ , ___ ___ , ___ ___ , ___

Replicates	Aerobic Spores							Aerobic Vegetative Cells							Fungi (Aerobic)							Actinomycetes (Aerobic)							Anaerobic Spores				Anaerobic Veg Cells				Other (Specify):							Total Aerobes	Total Anaerobes	Total Veg Cells	Total Spores	Total Population	Amt of Inoculum
	Inc. Temp	Method of Assay *	Medium *	Count at 24 Hr.	Count at 48 Hr.	Count at 72 Hr.	Reported Count	Inc. Temp	Method of Assay *	Medium *	Count at 24 Hr.	Count at 48 Hr.	Count at 72 Hr.	Reported Count	Inc. Temp	Method of Assay *	Medium *	Count at 24 Hr.	Count at 48 Hr.	Count at 72 Hr.	Reported Count	Inc. Temp	Method of Assay *	Medium *	Count at 24 Hr.	Count at 48 Hr.	Count at 72 Hr.	Reported Count	Inc. Temp	Method of Assay *	Medium *	Reported Count (72 H)	Inc. Temp	Method of Assay *	Medium *	Reported Count (72 H)	Inc. Temp	Method of Assay *	Medium *	Count at 24 Hr.	Count at 48 Hr.	Count at 72 Hr.	Reported Count						
1																																																	
2																																																	
3																																																	
4																																																	
5																																																	
6																																																	
7																																																	
8																																																	
9																																																	
10																																																	
Average																																																	
1																																																	
2																																																	
3																																																	
4																																																	
5																																																	
6																																																	
7																																																	
8																																																	
9																																																	
10																																																	
Average																																																	
1																																																	
2																																																	
3																																																	
4																																																	
5																																																	
6																																																	
7																																																	
8																																																	
9																																																	
10																																																	
Average																																																	

*CODES:

MEDIA
a. T.S.A.
b. B.H.I.
c. S.A.B.
d. E.M.B.
e. Eugon Agar
f. Clostrosil
g. ______
h. ______
i. ______
j. ______
k. ______
l. ______

METHOD OF ASSAY
a. Sonication
b. Washing
c. Rinsing
d. Lift-off tapes
e. Rodacing
f. Swabbing
g. Royco
h. Reynier
i. ______
j. ______
k. ______
l. ______

TYPE OF AREA
a. Work surface (bench, table top, etc.)
b. Wall
c. Floor
d. Ceiling
e. Air
f. ______
g. ______

ACTIVITY
a. Machining
b. Assembly
c. Solder, welding
d. Wiring
e. Transporting
f. Inspec.
g. Certif.
h. Mainten
i. Bioassay
j. ______
k. ______
l. No activity

FOLDOUT FRAME 1

FOLDOUT FRAME

FOLDOUT FRAME 2

FORM #_____ CMTM STERILIZATION PROGRAM ASSAY OF HARDWARE TABLE 4-7 PAGE ____ OF ____

ASSEMBLY OR PART NAME _____ NUMBER _____ NEXT HIGHER ASSEMBLY (NO.) _____ OPERATION NUMBER _____ DATE OF OPER. _____

MANUFACTURER _____ VENDOR _____ LOT _____ CODE OR SERIAL NUMBER _____ DATE REC'D _____

MATERIAL COMPOSITION _____ EXPERIMENTOR: _____ SUPERVISOR _____ DATE OF ASSAY _____

PERSONNEL PRESENT DURING OPERATION (Use reverse side if necessary):

ZONE _____ TYPE OF AREA* _____ AREA _____ square inches. VOLUME (IF INTERNAL AREA) _____ cubic inches. DISASSEMBLY* _____

Replicates	Aerobic Spores: Inc. Temp.	Method of Assay*	Medium*	Count at 24 Hr.	48 Hr.	72 Hr.	Reported Count	Aerobic Vegetative Cells (Veg. Count minus spore count): Inc. Temp.	Method of Assay*	Medium*	Count at 24 Hr.	48 Hr.	72 Hr.	Reported Count	Fungi (Aerobic): Inc. Temp.	Method of Assay*	Medium*	Count at 24 Hr.	48 Hr.	72 Hr.	Reported Count	Actinomycetes (Aerobic): Inc. Temp	Method of Assay*	Medium*	Count at 24 Hr.	48 Hr.	72 Hr.	Reported Count	Anaerobic Spores: Inc. Temp	Method of Assay*	Medium*	Reported Count (72 Hr)	Anaerobic Veg Cells: Inc. Temp	Method of Assay*	Medium*	Reported Count (72 Hr)	Other (Specify): _____ Inc. Temp.	Method of Assay*	Medium*	Count at 24 Hr.	48 Hr.	72 Hr.	Reported Count	Total Aerobes	Total Anaerobes	Tot. Veg. Cells	Total Spores	Total Population	Ant. of Inoculum
1																																																	
2																																																			
3																																																		
4																																																		
5																																																		
6																																																		
7																																																		
8																																																		
9																																																		
10																																																		
Average																																																		
1																																																		
2																																																		
3																																																		
4																																																		
5																																																		
6																																																		
7																																																		
8																																																		
9																																																		
10																																																		
Average																																																		

* CODES:

MEDIA

a.	T.S.A.	e.	Eugon Agar	i.	_____
b.	B.H.I.	f.	Clostrosil	j.	_____
c.	S.A.B.	g.	_____	k.	_____
d.	E.M.B.	h.	_____	l.	_____

METHOD OF ASSAY

a.	Sonication	e.	Rolacing	i.	_____
b.	Washing	f.	Swabbing	j.	_____
c.	Rinsing	g.	_____	k.	_____
d.	Lift-off tapes	h.	_____	l.	_____

TYPE OF AREA

a.	Surface	e.	Faying
b.	Occluded	f.	_____
c.	Internal	g.	_____
d.	Mated	h.	_____

METHOD OF DISASSEMBLY (If not a SURFACE area)

a.	Unbolting	e.	Sectioning	i.	Unwraping
b.	Cutting	f.	Splitting	j.	Sawing
c.	Grinding	g.	Drilling	k.	_____
d.	Crushing	h.	Dissolving	l.	_____

FOLDOUT FRAME 1

F-5/F-6

FOLDOUT FRAME 2

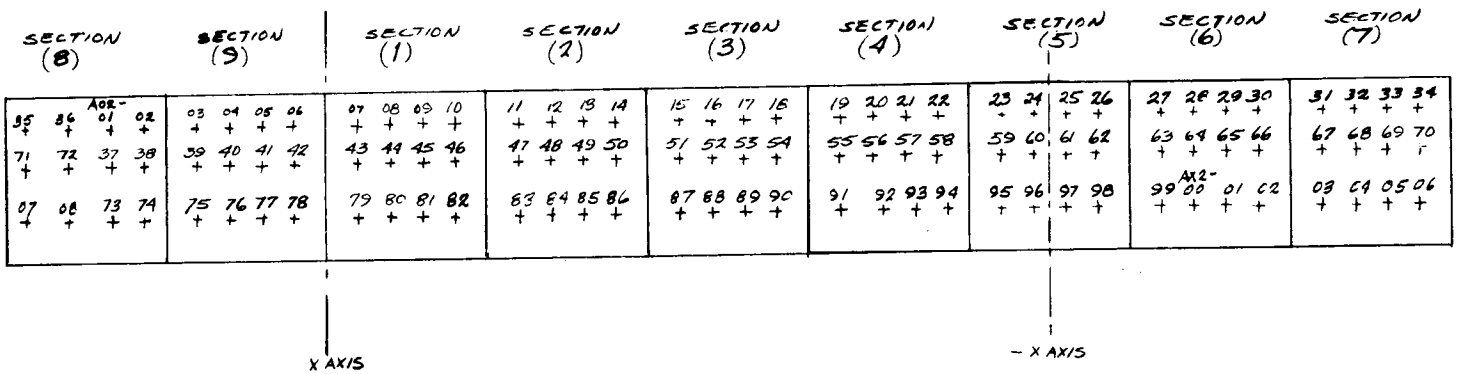
APPENDIX G

ILLUSTRATIONS OF COUPON LOCATIONS

FIGURE 4-8
AEROSHELL
(SIDE VIEW)

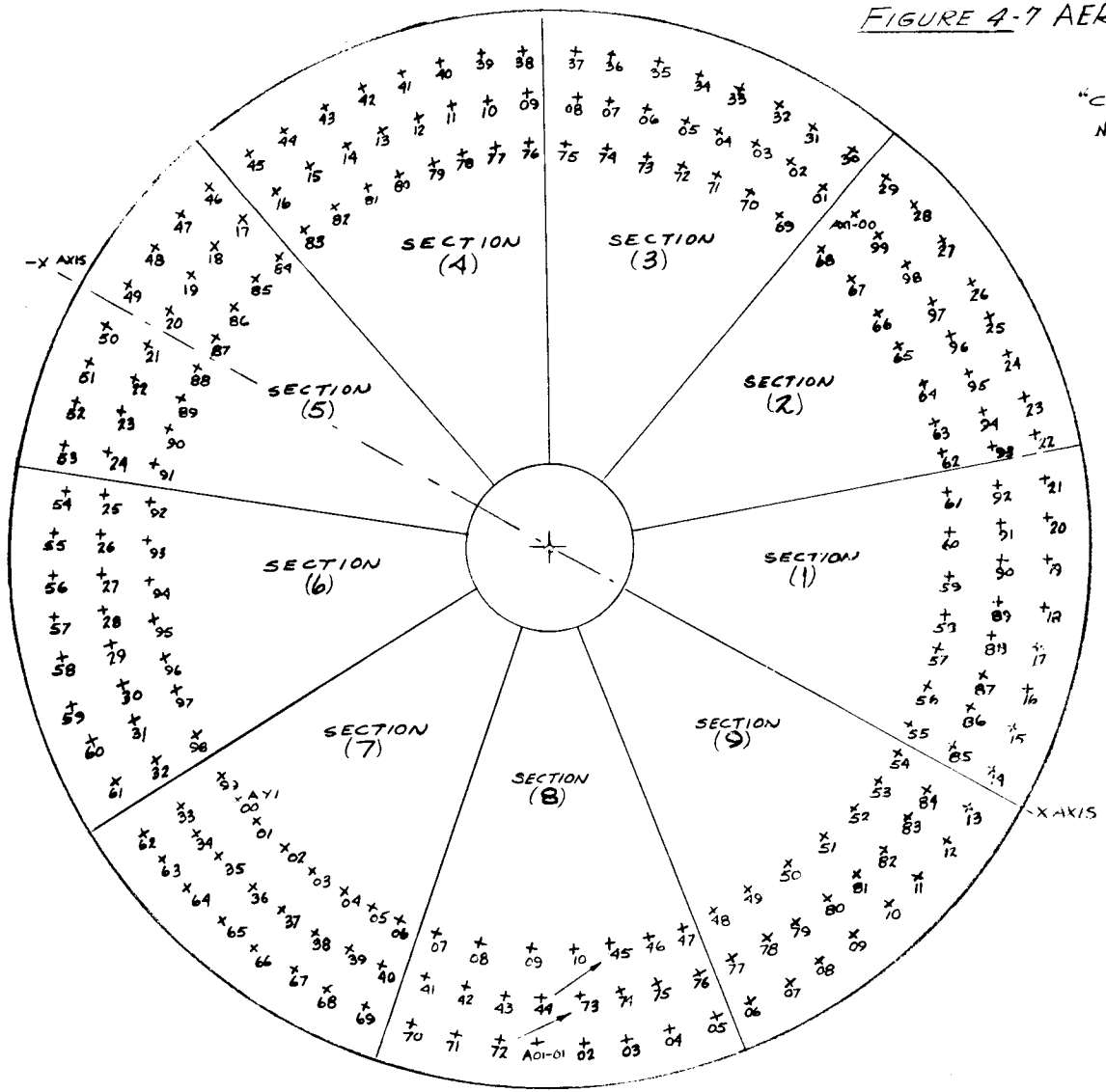
"COUPON DISTRIBUTION"
NO's A02-01 - A02-99
AX2-00 - AX2-08

OUTSIDE CYLINDRICAL SURFACE



G-4

FIGURE 4-7 AEROSHELL
(TOP VIEW)



"COUPON DISTRIBUTION"

NO.'s A01-01 TO A01-99
AX1-00 TO AX1-99
AY1-00 TO AY1-10

OUT SIDE SURFACE (FRUSTRUM WITH CONICAL APEX)

FIGURE 4-9 AEROSHELL
(SUPPORT RING, INSIDE)

SIDE VIEW

"COUPON DISTRIBUTION"
NO's A03-01 TO A03-30
A04-01 TO A04-32
A05-01 TO A05-30
A06-01 TO A06-30

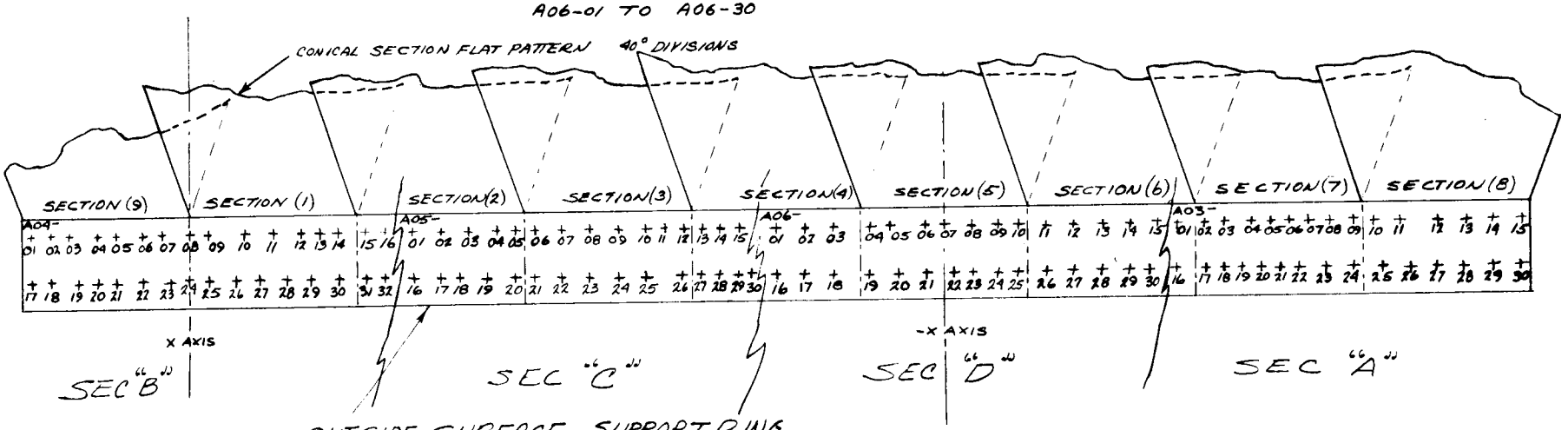


FIGURE 9-10 AEROSHELL
(SUPPORT RING, INSIDE)
SIDE VIEW

"COUPON DISTRIBUTION"
Nos A07-01 TO A07-03
A09-01 TO A09-03

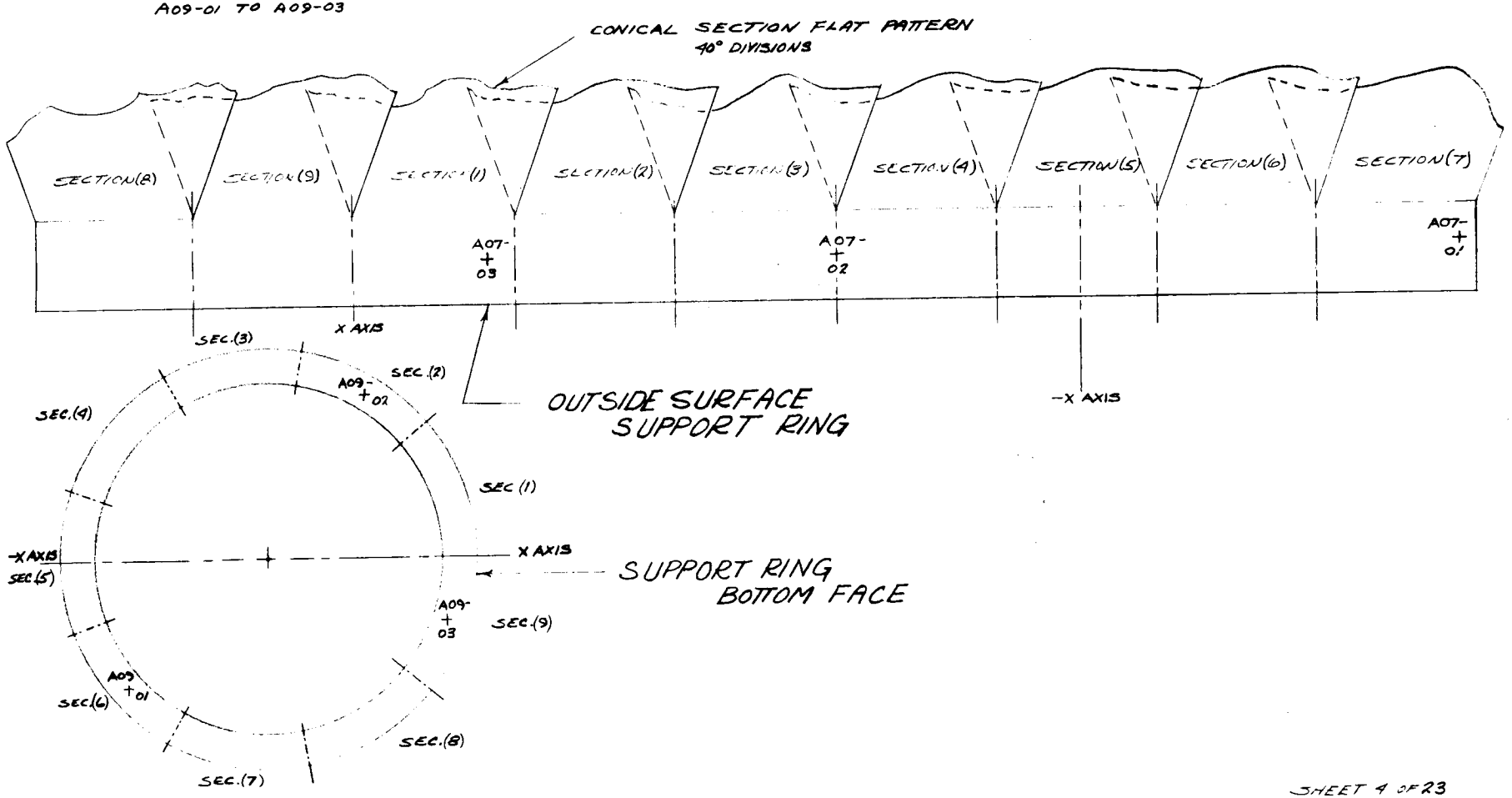
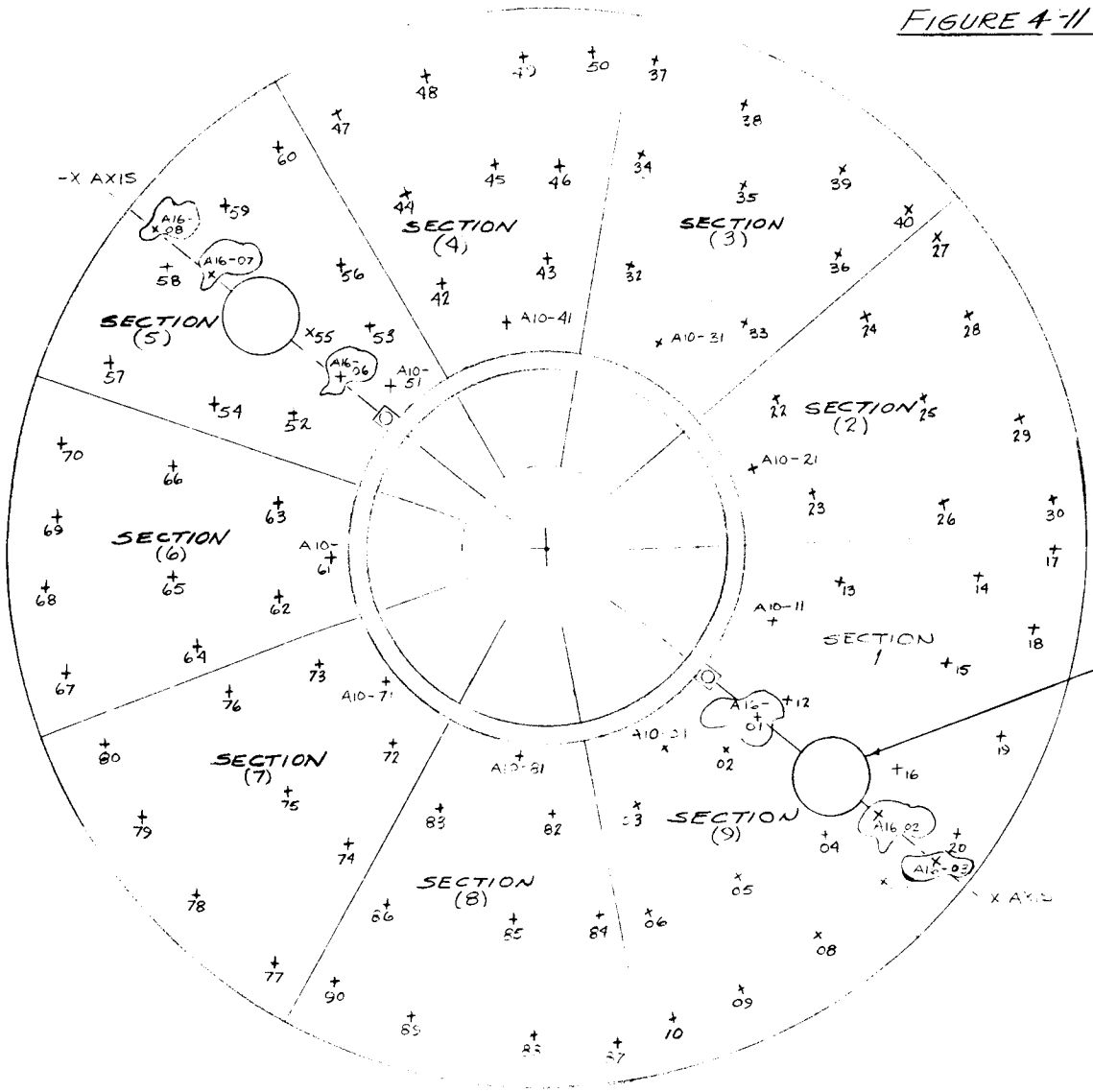


FIGURE 4-11 AEROSHELL

(UNDER SIDE VIEW)

"COUPON DISTRIBUTION"
NO's A10-01 TO A10-90
A16-01 TO A16-03
A16-06 TO A16 08



INSIDE SURFACE (FRUSTRUM WITH CONICAL APEX)

FIGURE 4-12

AEROSHELL (SIDE VIEW EXTENDED)

"COUPON DISTRIBUTION"

NOS A11-01 TO A11-90

A16-01 TO A16-05

A16-09 TO A16-10

INSIDE SURFACE CYLINDRICAL SECTION

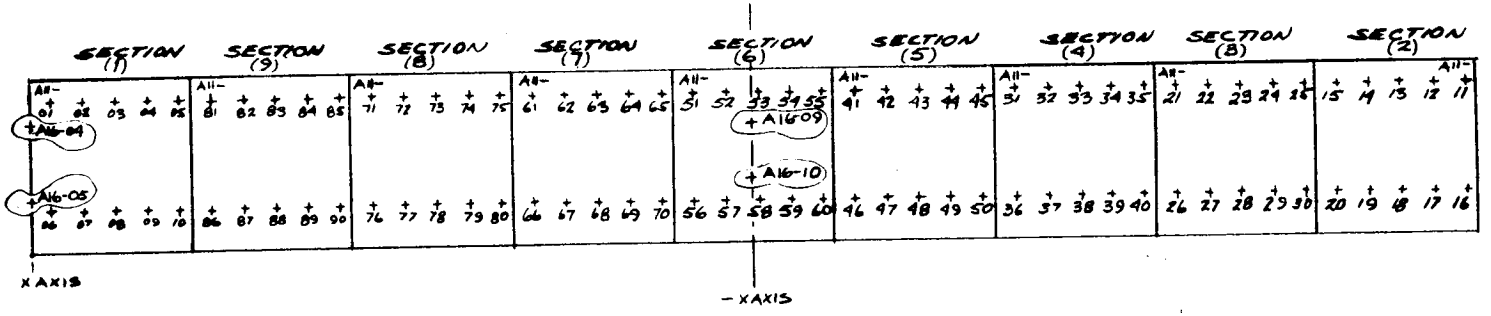
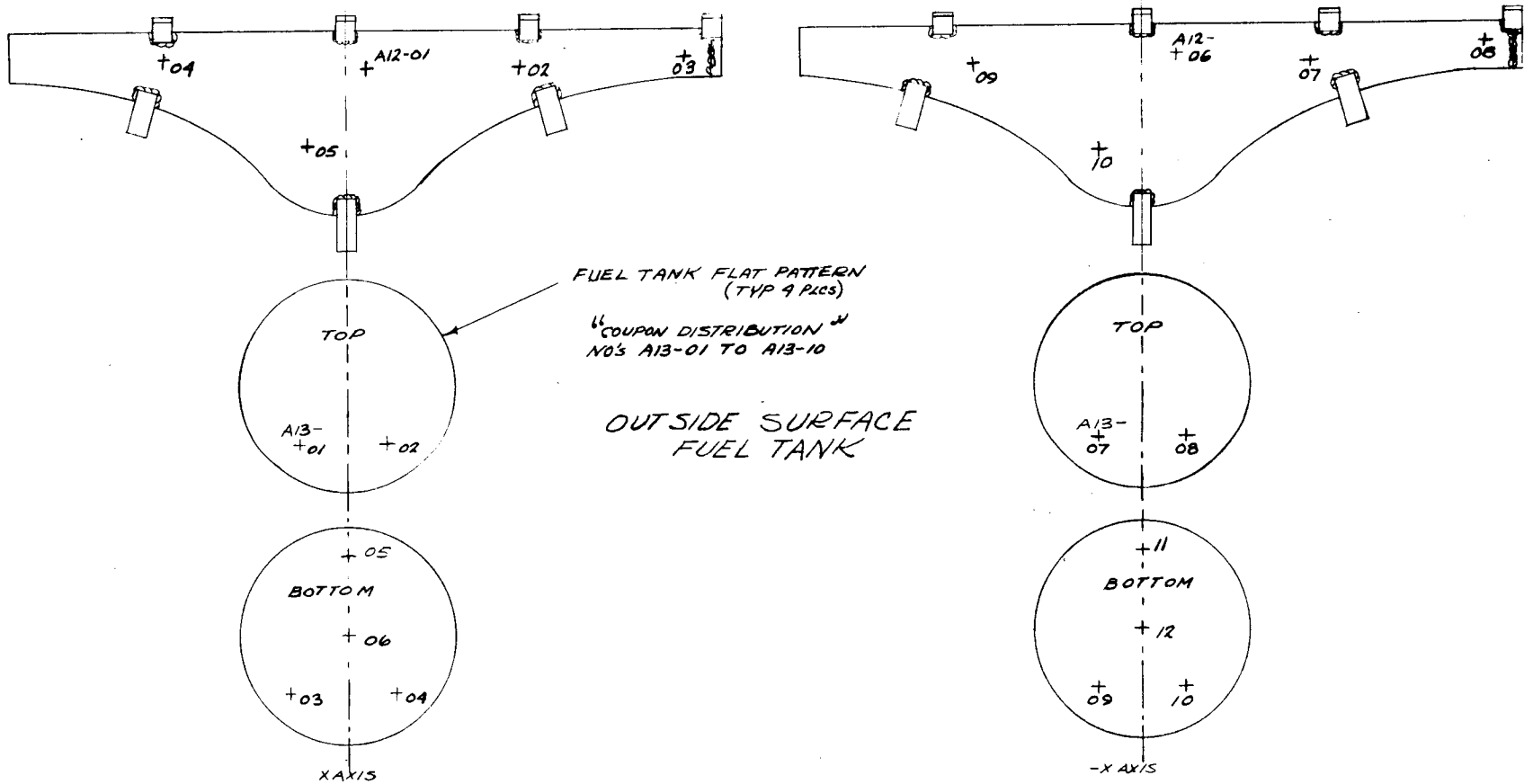


FIGURE 4-13 AEROSHELL -INSIDE-

(ATTITUDE CONTROL FUEL TANK BRACKETS)

"COUPON DISTRIBUTION" NO'S A12-01 TO A12-10

OUTSIDE SURFACE

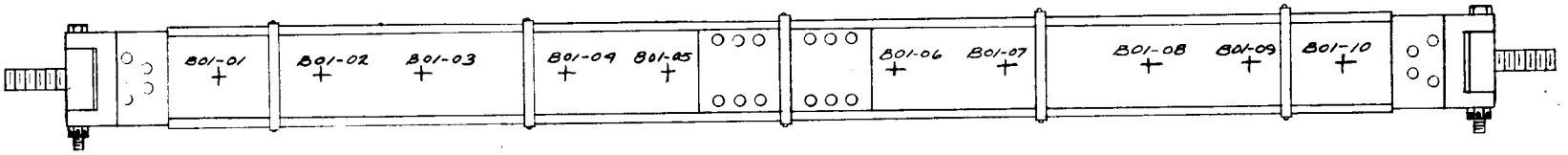


OUTSIDE SURFACE FUEL TANK

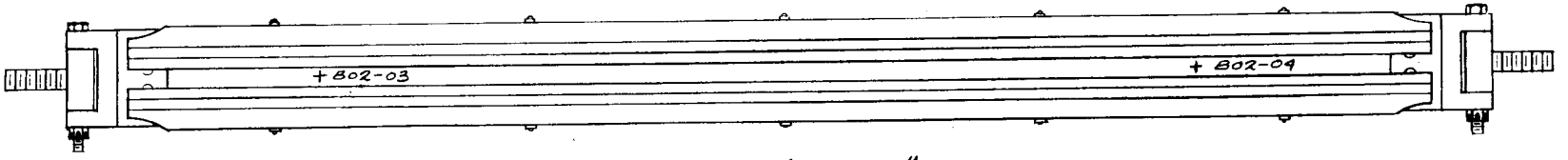
FIGURE 1-19 MARMON CLAMP (FLAT PATTERN)

"COUPON DISTRIBUTION"
NO'S B01-01 TO B01-20
B02-01 TO B02-04
B03-01 TO B03-02

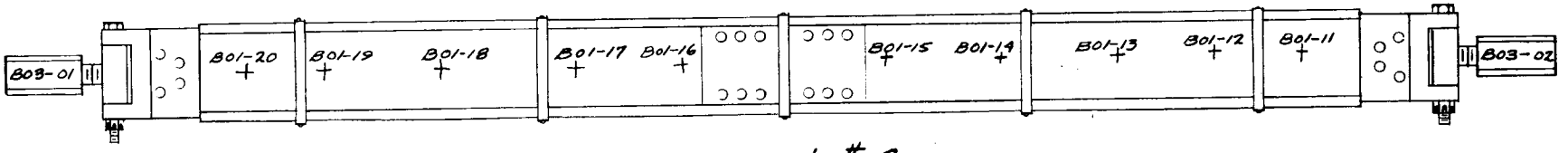
FRONT VIEW #1



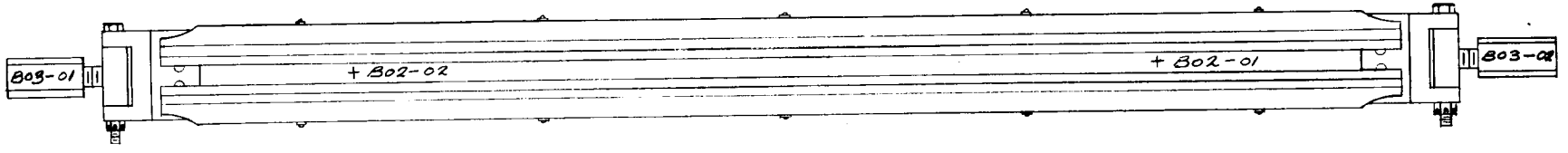
BACK VIEW #1



FRONT VIEW #2



BACK VIEW # 2



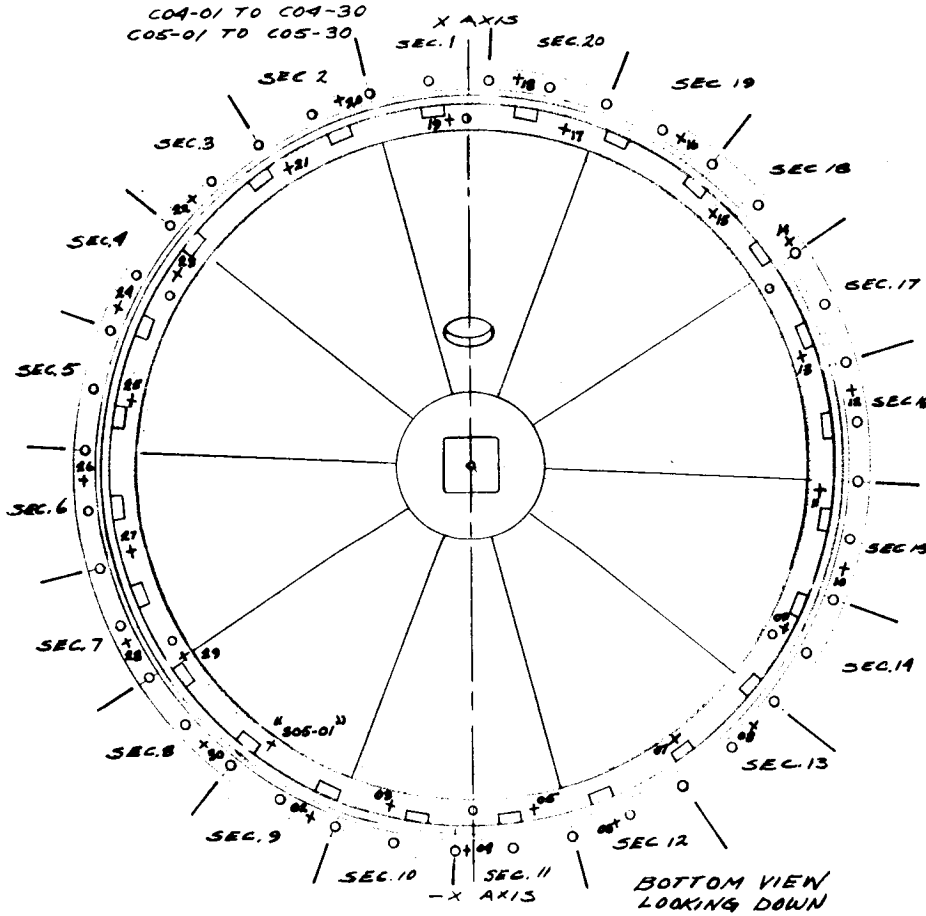
G-10

SHEET 8 OF 23

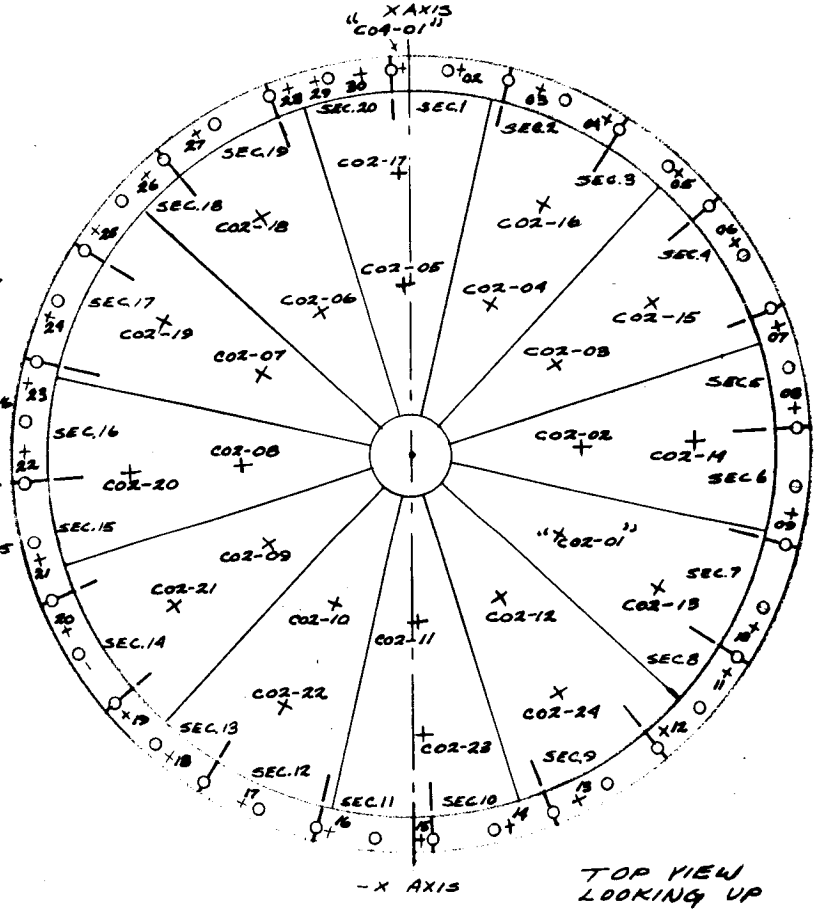
FIGURE 4-15 CANISTER

"COUPON DISTRIBUTION" (TOP & BOTTOM HALVES)

NO's C02-01 TO C02-24
C04-01 TO C04-30
C05-01 TO C05-30



BOTTOM VIEW
LOOKING DOWN



TOP VIEW
LOOKING UP

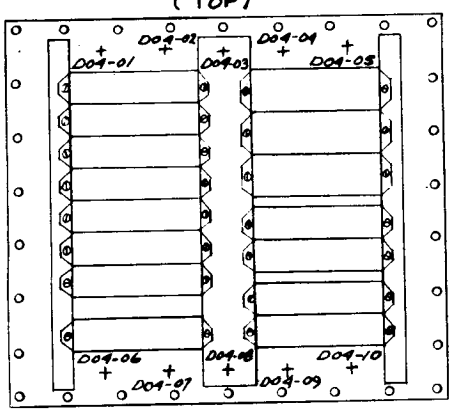
FIGURE 4-16
DUMMY CHASSIS

"COUPON DISTRIBUTION"
NO's D01-01 TO D01-84
D02-01 TO D02-70
D04-01 TO D04-70

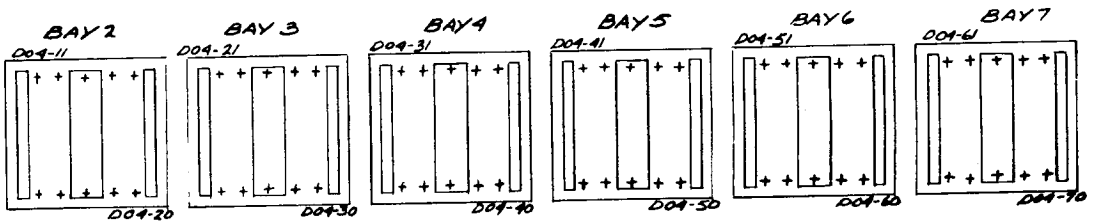
BAY 1

(TOP)

BACK VIEW

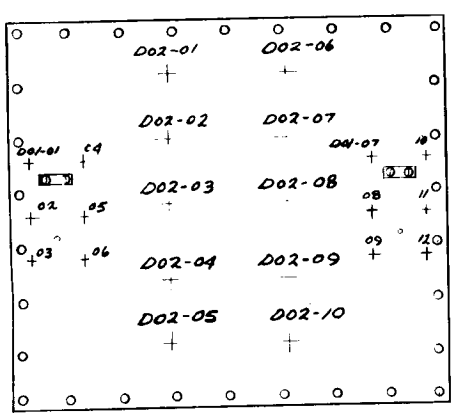


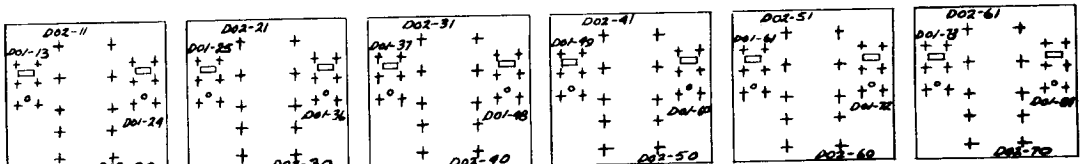
NOTE:
CHASSIS NO's 1 THRU 7 ARE NUMBERED CONSECUTIVELY AS PER DRAWINGS. EACH COUPON POSITION (+) IS THE SAME THRU OUT, IN STEPS OF 10 & 12



(INSIDE SURFACES)

FRONT VIEW





(OUTSIDE SURFACES)

FIGURE 4-17 LIVE CHASSIS

"COUPON DISTRIBUTION"
NOS D06-01 TO D06-12
D07-01 TO D07-10
D09-01 TO D09-10

BAY 8

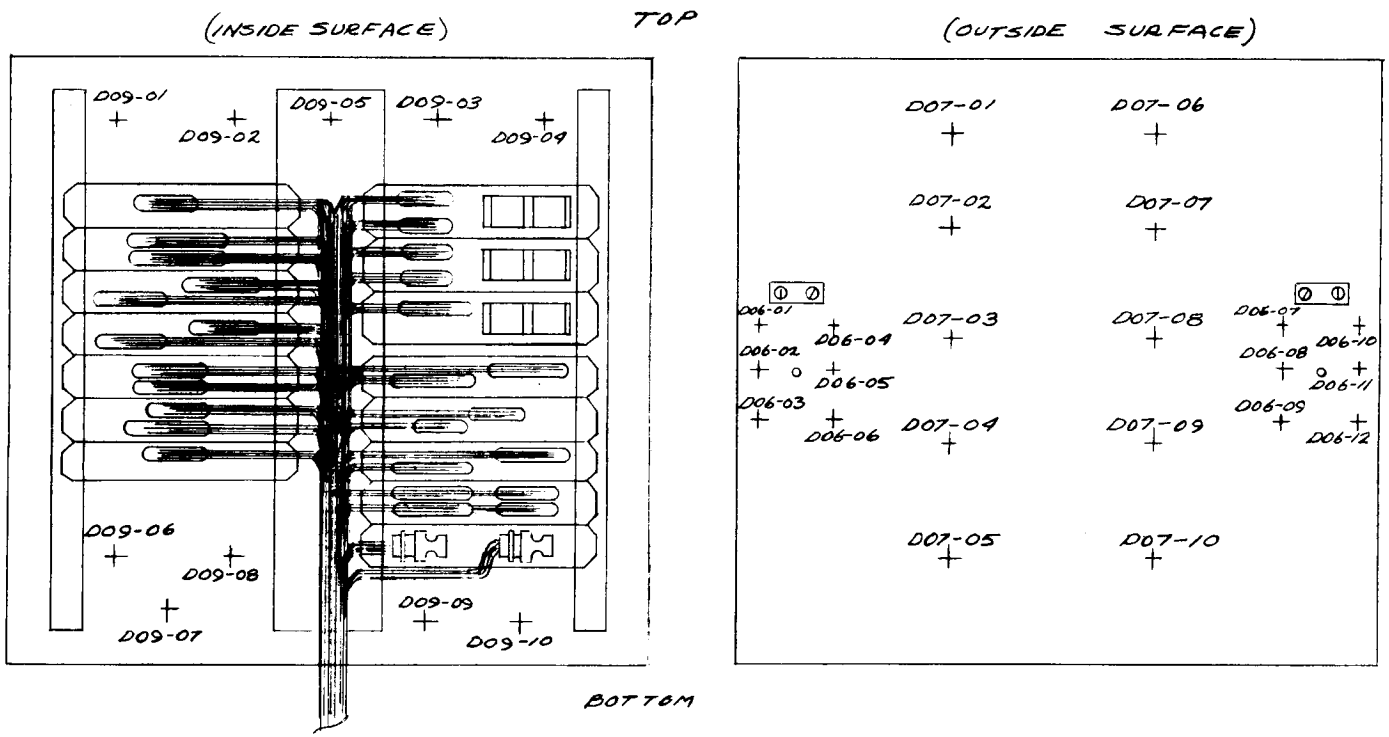
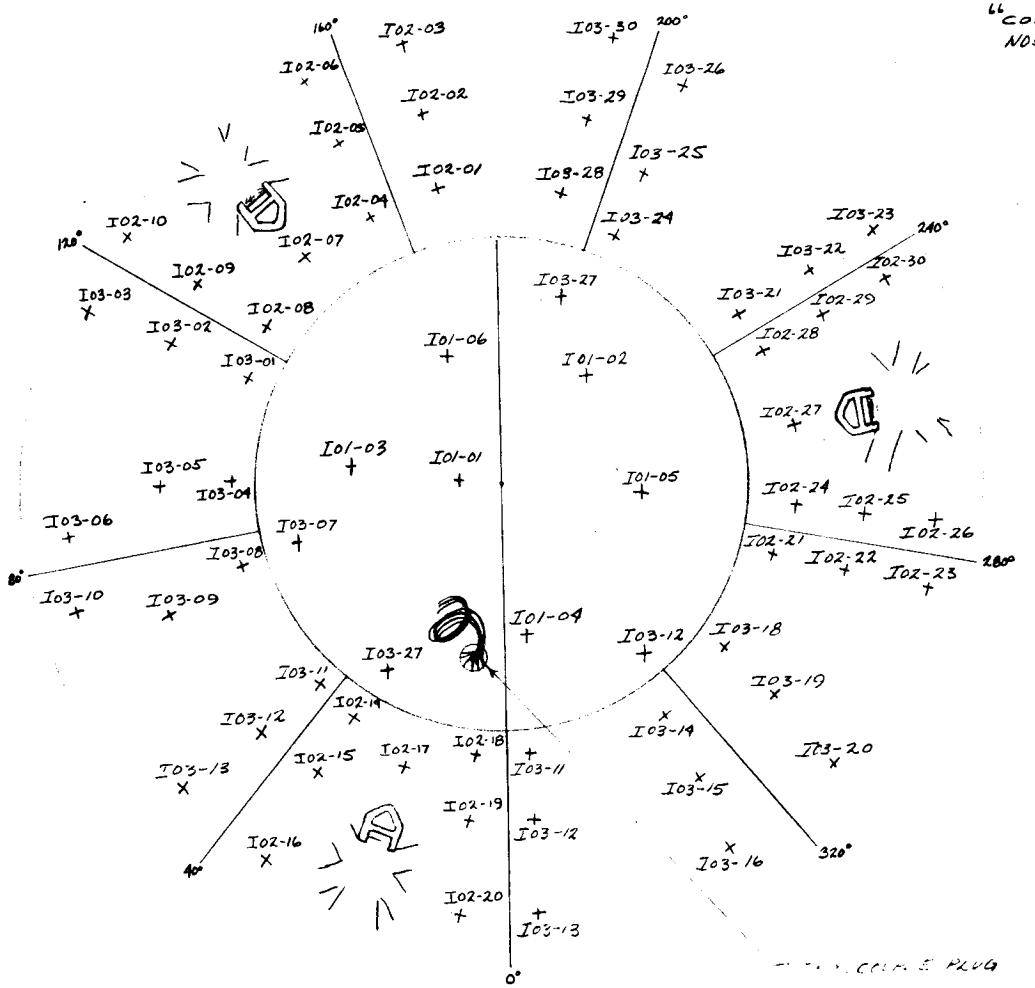


FIGURE 4-18
IMPACT LIMITER
(TOP VIEW)

"COUPON DISTRIBUTION"
NO's I01-01 TO I01-06
I02-01 TO I02-30
I03-01 TO I03-30

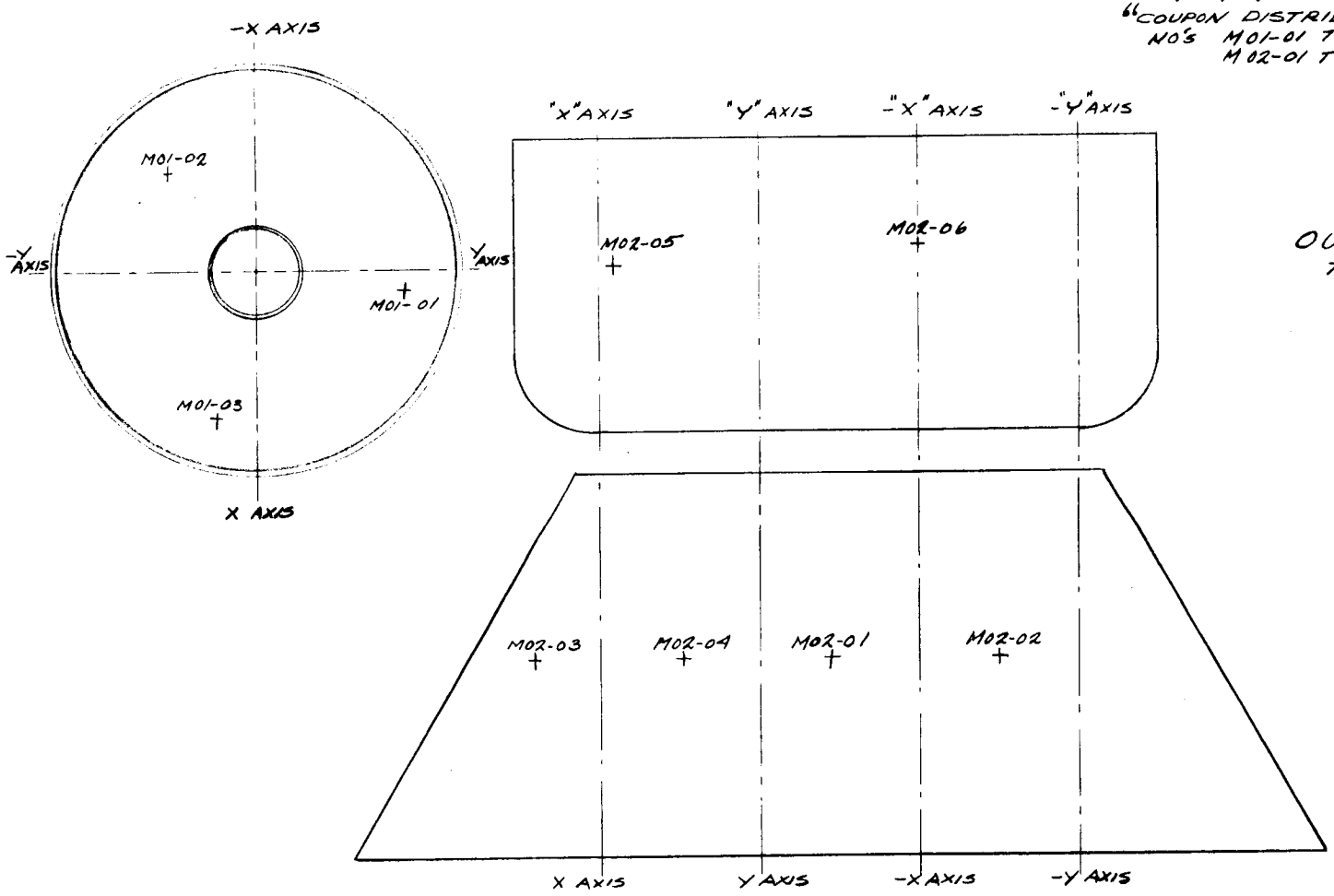


OUTSIDE SURFACE
(TOP HALF)

...COIL SPRING PLUG

FIGURE 4-19 DE-ORBIT MOTOR TOP & SIDE VIEW

"COUPON DISTRIBUTION"
NO'S M01-01 TO M01-03
M02-01 TO M02-06



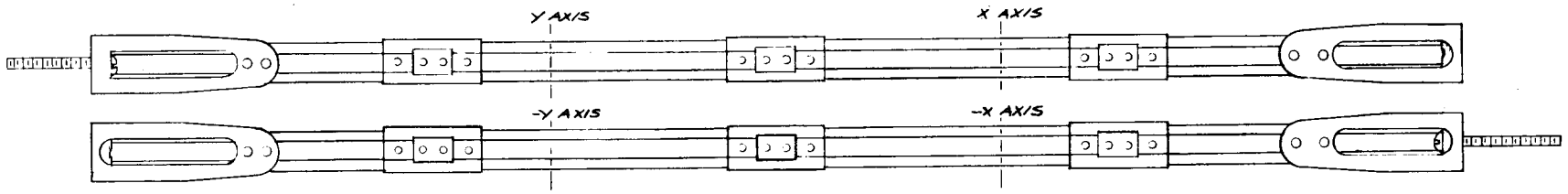
OUT SIDE SURFACE
TOP & SIDE

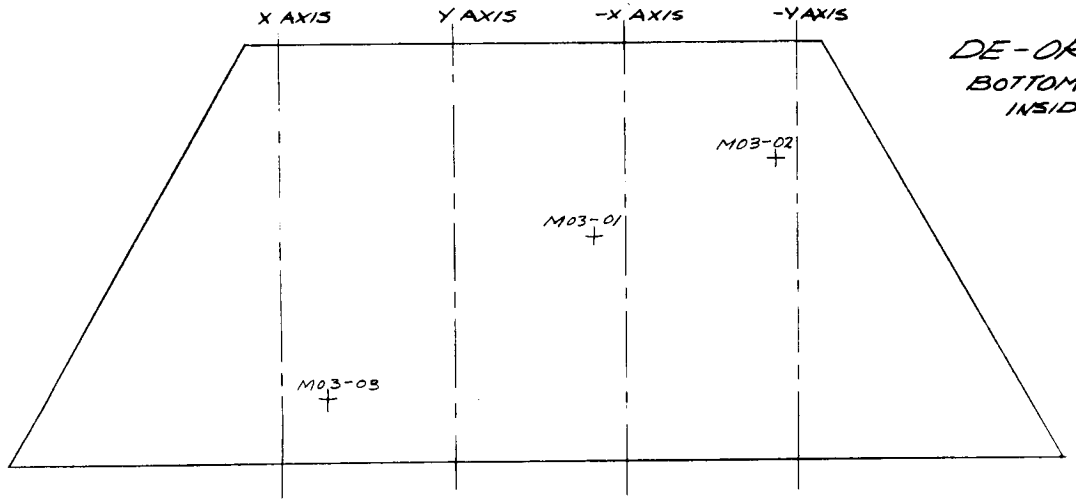
FIGURE 4-20 DE-ORBIT MOTOR CLAMP & MOTOR BOTTOM

"COUPON DISTRIBUTION"
No's 001-01 TO 001-04
M03-01 TO M03-03

CLAMPS
SIDE VIEW

BOTH HALVES FLAT PATTERN





DE-ORBIT MOTOR
BOTTOM FRUSTRUM
INSIDE FLAT PATTERN

G-16

FIGURE 4-21
DE-ORBIT MOTOR CABLE HARNESS

COUPON DISTRIBUTION
NO'S M04-01 TO M04-10
M05-01 TO M05-02
U02-06

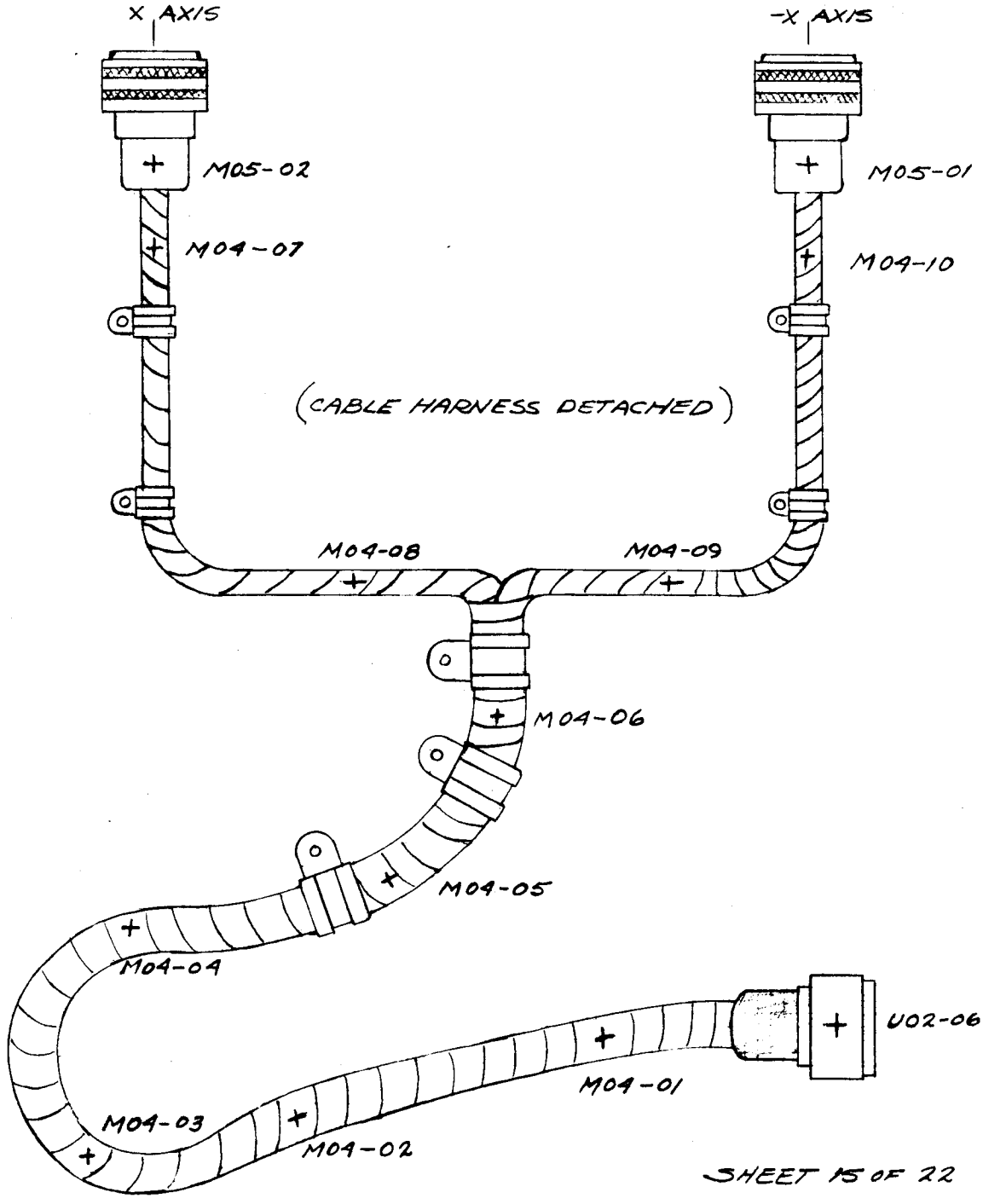


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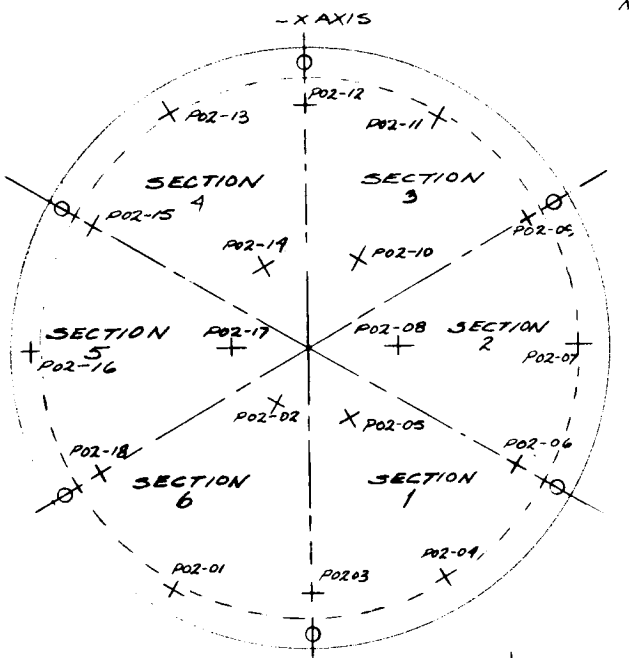
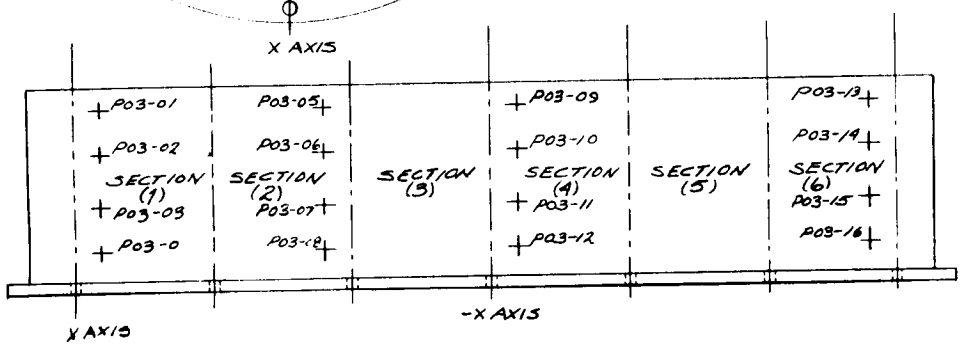
FIGURE 4-22 PARACHUTE CANISTER
2 VIEWS

"COUPON DISTRIBUTION"
NO's P02-01 TO P02-18
P03-01 TO P03-16



CANISTER BOTTOM VIEW (OUTSIDE SURFACE)



CANISTER SIDE VIEW (OUTSIDE SURFACE)

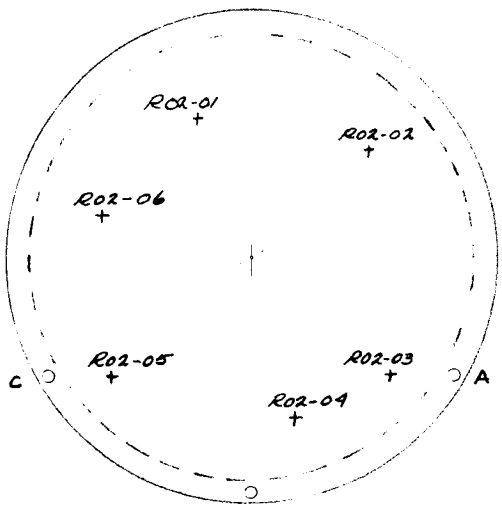
FIGURE 4-23 ANTENNA (TRI-VIEW)

"COUPON DISTRIBUTION"

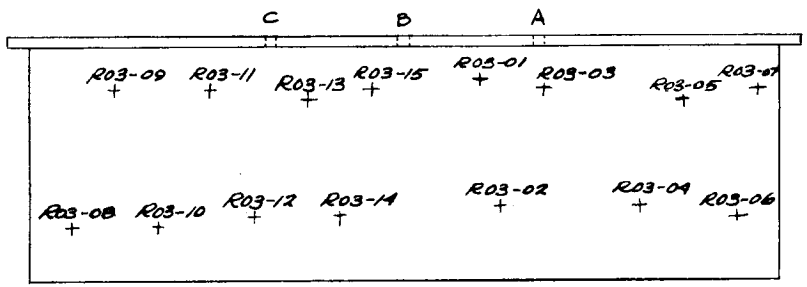
[illegible]-01 [illegible]

R0[illegible]01 TO R02-[illegible]

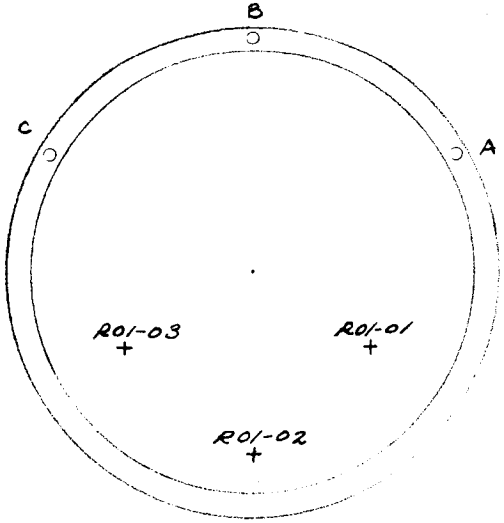
R03-01 TO R03-15



BOTTOM VIEW



SIDE VIEW



TOP VIEW

G-19

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FIGURE 4-24
PAYLOAD CHASSIS
"COUPON DISTRIBUTION"
NO'S S01-01 TO S01-08
S02-01 TO S02-64
S08-01 TO S08-46

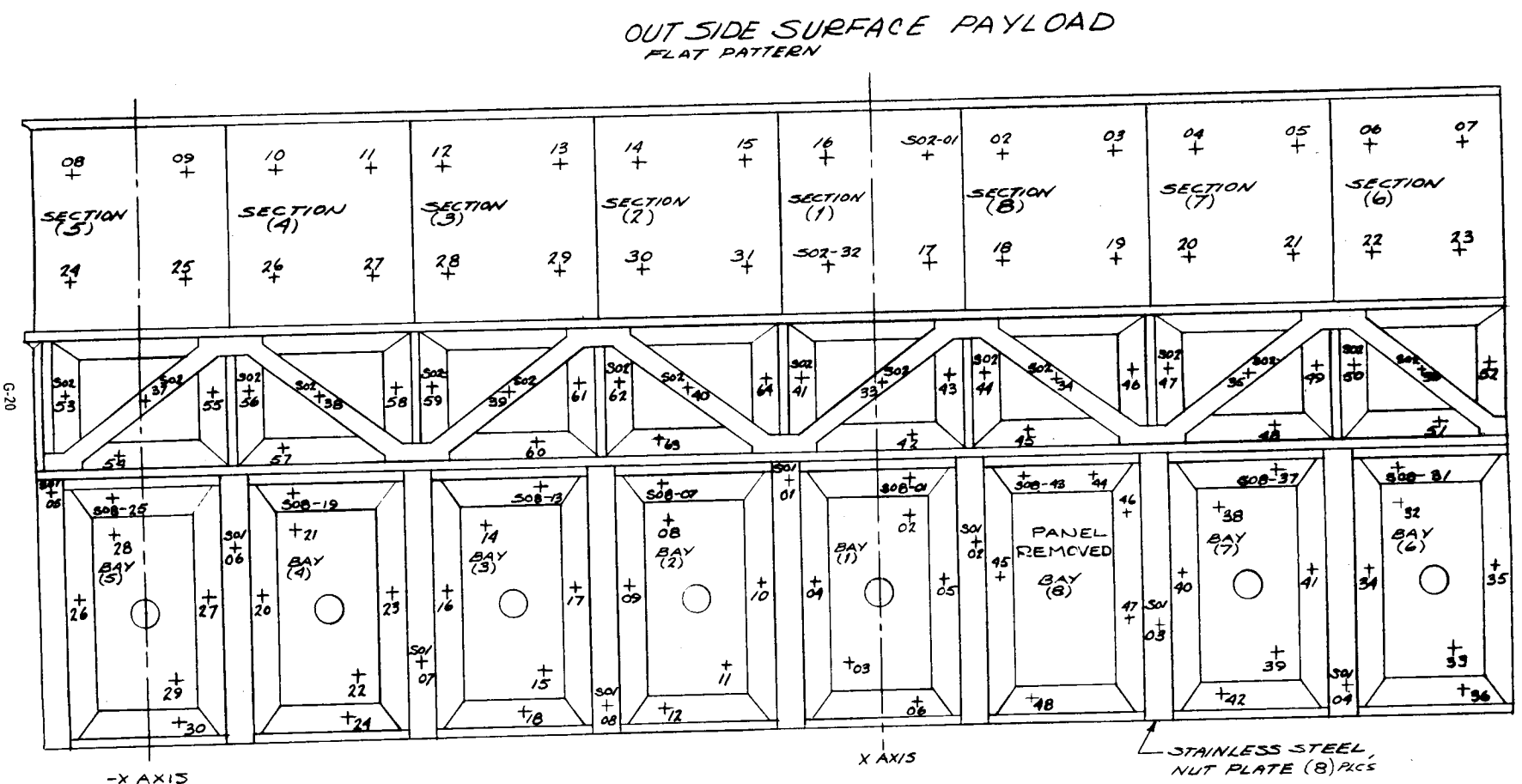
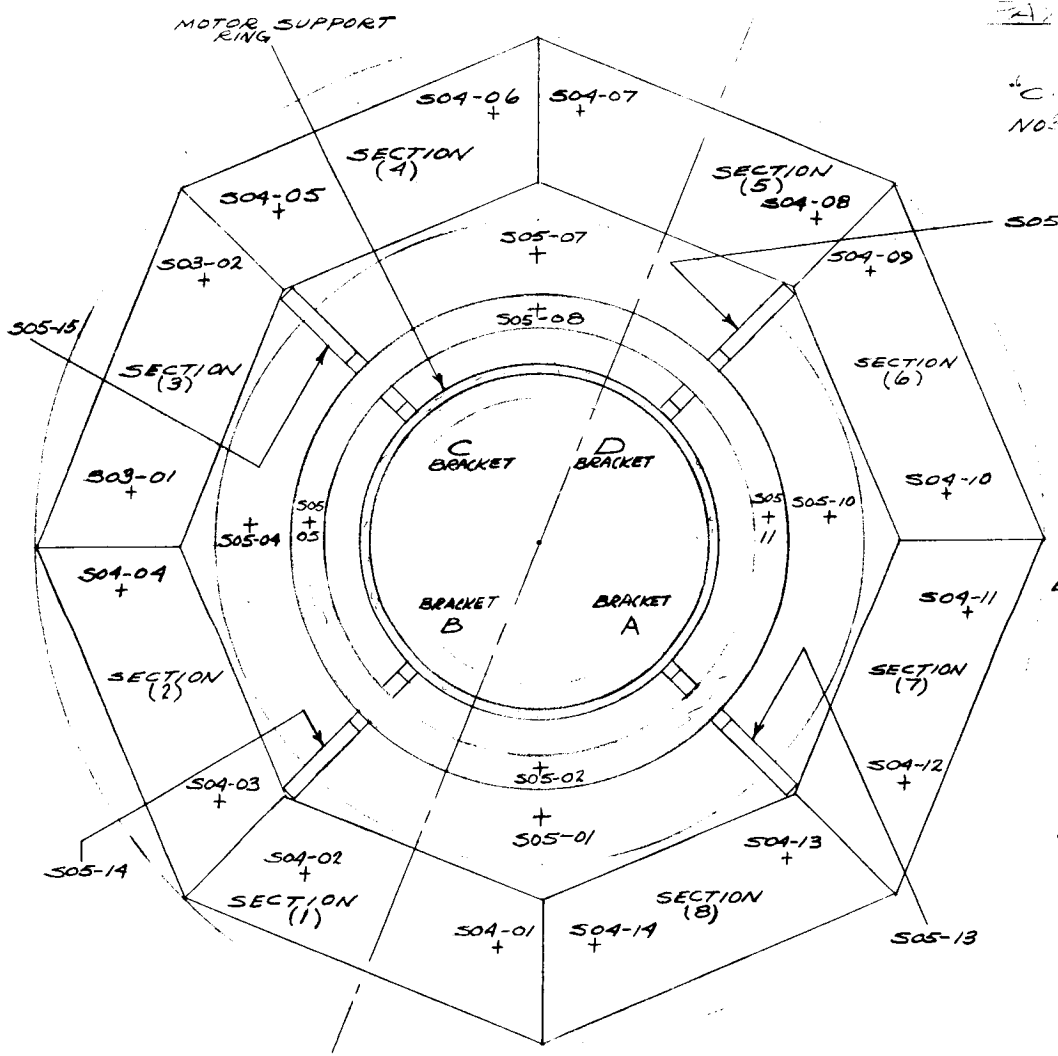


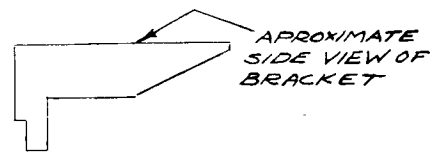
FIGURE 4-25

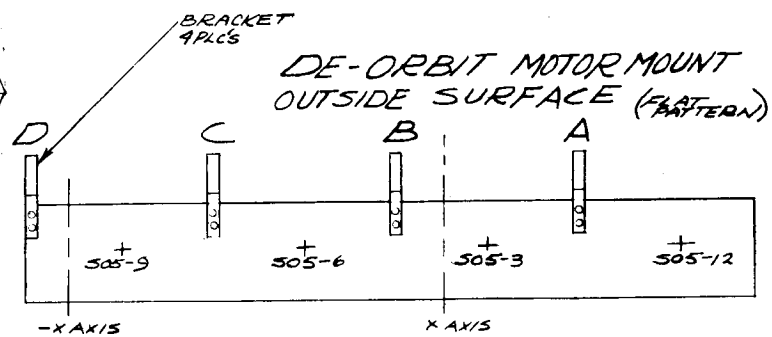
PAYLOAD (BOTTOM VIEW LOOKING UP)

*COUPON DISTRIBUTION

NOTE	503-01	TO	503-2
	504-01	TO	504-
	505-01	TO	505-16
	507-01	TO	507-8







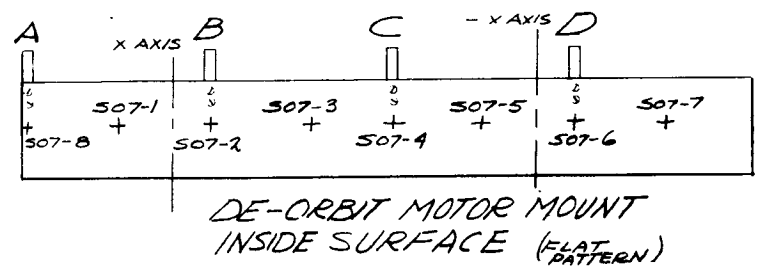


FIGURE 4-26 PAYLOAD

(TOP VIEW LOOKING DOWN)

"COUPON DISTRIBUTION"
NO's S06-01 TO S06-06
S11-01 TO S11-06
S12-01 TO S12-06

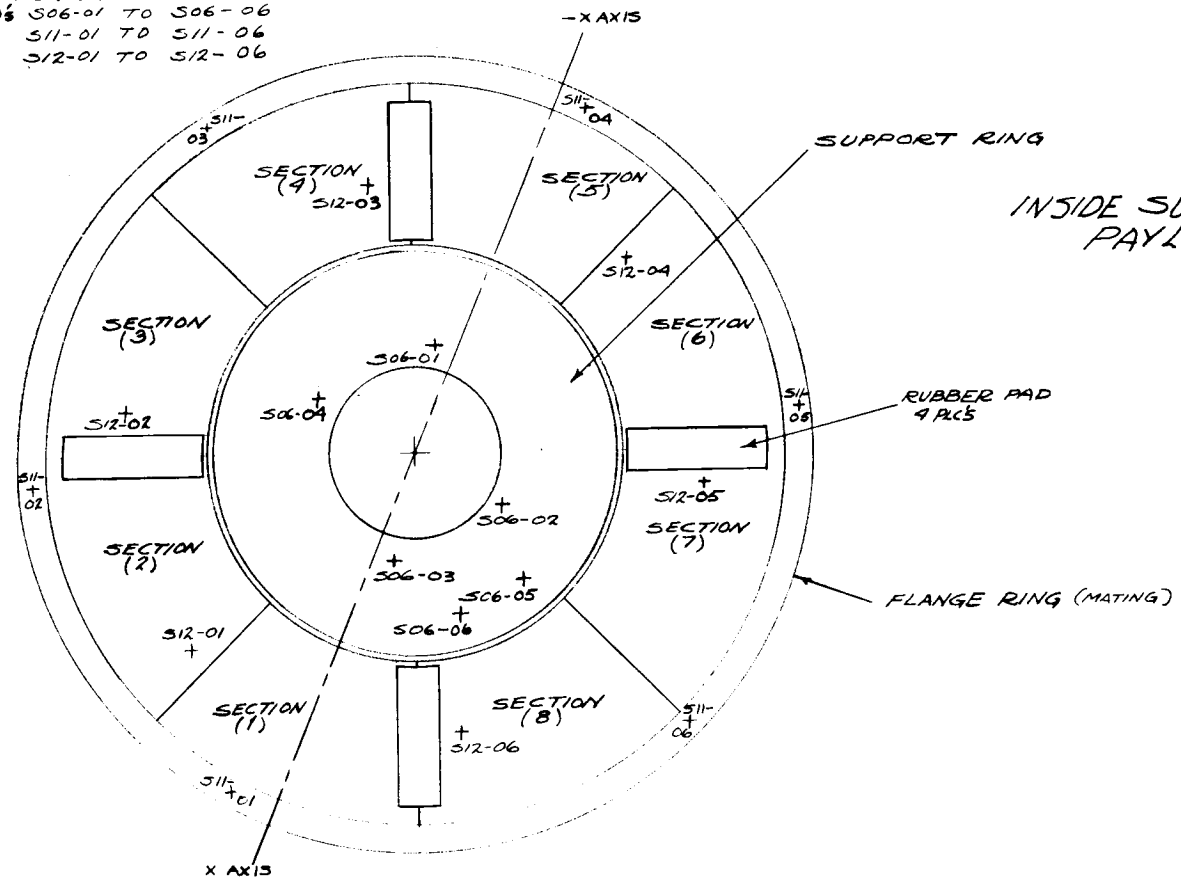
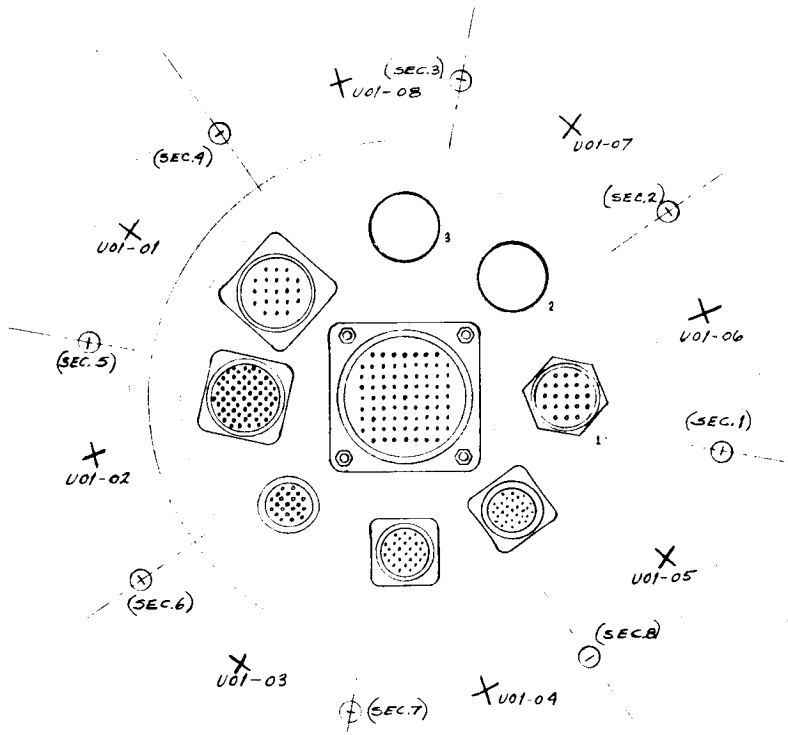


FIGURE 4-21 UMBILICAL PLATE

"COUPON DISTRIBUTION"
NO's U01-01 TO U01-21



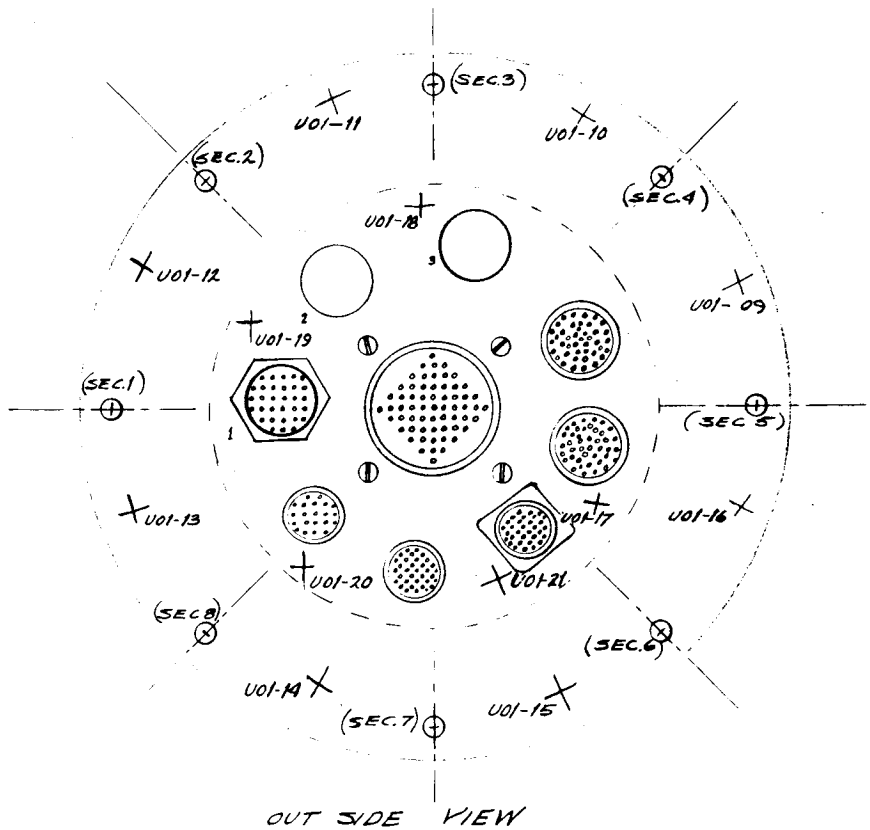
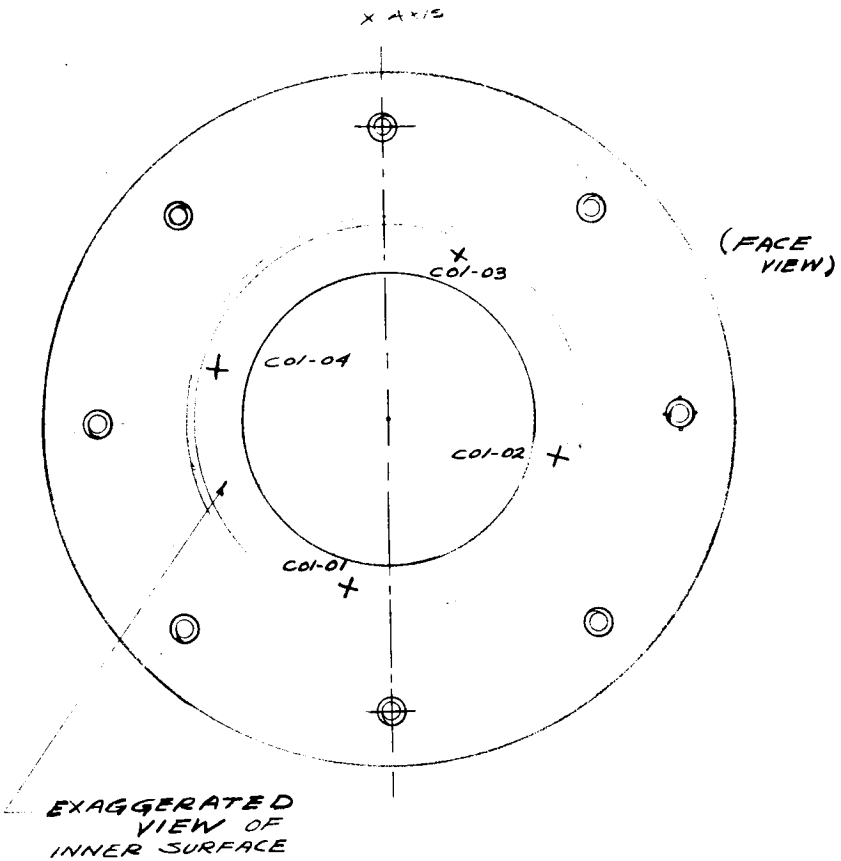


FIGURE 4-28 UMBILICAL FLANGE CONNECTION

"COUPON DISTRIBUTION"
NO'S C01-01 TO C01-04



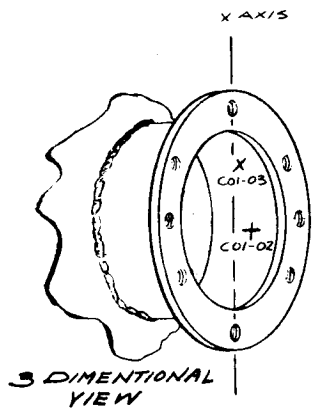
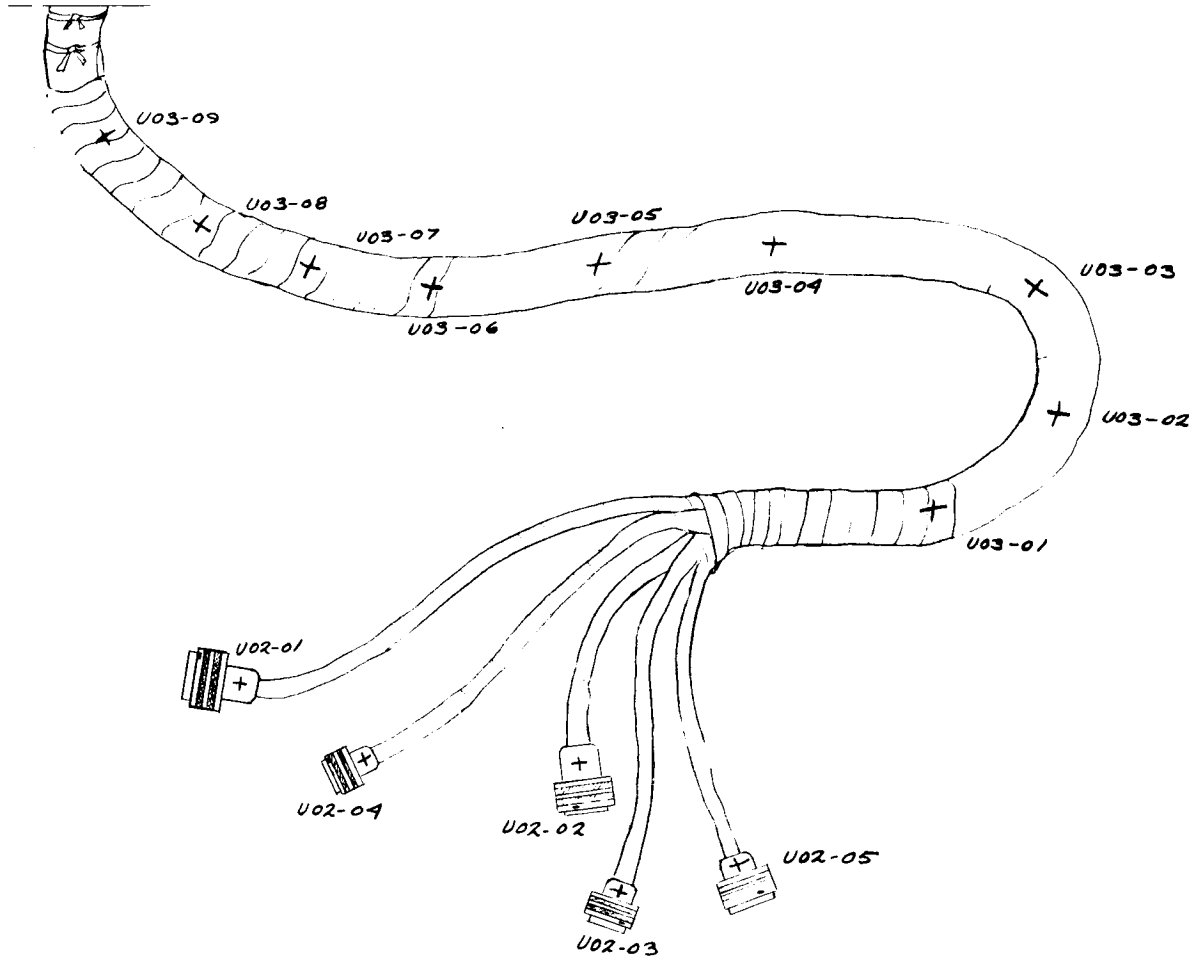


FIGURE 4-29

BAY 8 UMBILICAL HARNESS

"COUPON DISTRIBUTION"
NO'S U02-01 TO U02-05
U03-01 TO U03-09



PART 5

THE DEVELOPMENT OF PROCEDURES NECESSARY FOR VERIFYING STERILITY OF THE ASSEMBLED CMTM

I. INTRODUCTION

The objective of this task is to provide certified evidence that the CMTM and the inner surface of the sterilization canister are sterile within the limits set forth by NASA. This planetary quarantine requirement states that the probability of a single viable organism being upon a spacecraft intended for penetration of the Martian atmosphere, of for landing upon Mars, shall be less than one in 10^{-4}(1). To verify that this requirement has been met, the total microbial burden on the CMTM just prior to terminal sterilization will be estimated by utilizing the burden prediction procedures used in previous sub-tasks. Also to be considered in arriving at a microbial burden estimate will be Q. A. and other appropriate documents and records. This microbial load includes internal, surface, and occluded microorganisms. The CMTM is then sealed in its sterilization canister and exposed to a terminal heat sterilization cycle for that time necessary to sterilize the CMTM to the required probability level. The terminal heat process will decrease the microbial burden by an n number of D values (dependent upon temperature and length of process) to furnish the required degree of sterility.

The thermal profile of the CMTM and canister will be monitored by thermocouples during terminal sterilization. The resulting data obtained from the thermocouples will be automatically recorded on strip charts (Honeywell recorder). All procedures concerning CMTM terminal sterilization will be documented and verified under the supervision of Quality Assurance personnel.

The effect of the thermal process on the microbial burden can best be determined by an actual examination of a chemical reaction that is rate controlled by a catalyst. There are a number of excellent examples; however, one example will be sufficient to illustrate that the method is practicable. By the static chemical indicator method, Quality Assurance and Microbiology can establish that the thermocouple data is verified in terms of a chemical reaction necessary to support biological systems.

II. APPROACH

The method adopted to verify sterility of the CMTM can be essentially divided into three parts, which include:

1. Estimation of the microbial burden on the assembled CMTM.
2. Derivation of a terminal sterilization cycle.
3. Verification of the terminal sterilization cycle.

The methods and procedures to be used for estimating the microbial burden on the CMTM prior to terminal sterilization are discussed in Part 4. Utilizing these methods, a microbial burden estimate for the various CMTM zones can be obtained and the distribution of the microorganisms known. A terminal sterilization cycle may therefore be calculated which considers the effects of microbial distribution upon the total process time required by apportioning the probability of survival to each distribution zone and establishing a terminal sterilization cycle which will effectively sterilize the (thermally) most inaccessible zone. The sterilization cycle utilizing dry-sterile Nitrogen will be monitored with thermocouples and other instruments as deemed necessary.

Thermocouples placed on the CMTM can verify that the CMTM was exposed to the minimum D values (a "D" during the length of time necessary to reduce the microbial burden by 90%) at the thermocouple location sites only necessary to guarantee sterility to the desired probability.

Thermocouples will be mounted on the CMTM and joined by means of leads to an umbilical connector plate. The umbilical connector plate will then be connected to strip chart recorders by means of a special harness. The entire process will be monitored by Q. A. who will verify the calibration of the thermocouples and recorders.

The chemical indicator method, presented in Appendix 1, is a feasible verification reaction to put thermocouple verification data in terms of microbiology.

The thirty-nine thermocouples to be placed on the CMTM are located as follows:

1. 8 thermocouples on the canister as described:
   a. One on the external apex and one on the internal apex.
   b. One on the X axis and on the -X axis 1-1/2" up from the lip of the canister.
   c. One on the interior and one on the exterior of the canister. 40" from the bottom lip of the canister on the X axis.
   d. One on the exterior and one on the interior of the canister 37" from the bottom lip of the canister on the X axis

2. 3 Thermocouples on the Aeroshell as described below:
   a. One on the internal section 40" from the bottom lip of the Aeroshell on the X axis.

3. 2 Thermocouples on the de-orbit motor per instructions:
   a. One on the X axis 15" down from the connector ring inside of motor.
   b. One on the -X axis 15" down from the connector ring inside of motor.
   c. One thermocouple on the ring that connects the motor to the cone at the -X axis.

4. 2 Thermocouples on the Attitude Control Tank.
   a. One on each of the control tanks as follows:
   Measure from X to -X axis, then measure from Y to -Y axis and place the thermocouple where the lines cross.

5. 4 Thermocouples on the bays as follows:
   a. One on Bay 2 module (6A27) area (JL).
   b. One on Bay 3 module (6A27) area (JL).

c. One on Bay 5 module (6A7) area (JL).

d. One on Bay 7 module (6A6) area (JL).

6. 4 Thermocouples on the Parachute Canister.

a. One on the X axis 8" down from the top edge of canister.

b. One on the-X axis 8" down from the top edge of canister.

c. One on the bottom of the canister in direct center.

d. One on the surface of the tank 8" down from top edge.

7. 2 Thermocouples on the antenna as follows:

a. One on the antenna 8" from the edge of the antenna toward the center, on the X axis on the bottom of the antenna.

b. One in the inside probe of the antenna.

8. 4 Thermocouples on the bays 2, 3, 5, 7 outside surface as follows:

a. Measure from the top edge to the center of the bay which is 10", then measure from the side edge to center which is 9". Place one thermocouple on each of the four bays 2, 3, 5 and 7.

9. 8 Thermocouples in the balsa wood impact limiter.

10. 1 Thermoooupleinthe parachute canister.

In this manner the thermal profile of the CMTM can be established. With this knowledge (the thermal profile on the craft, the microbial load and its distribution, and the characteristics of the heating medium) it is possible to derive a terminal sterilization cycle tailored for the CMTM. Three alternate approaches to the derivation of a terminal cycle have been considered and include:

1. A dry heat terminal sterilization cycle for the CMTM with consideration of the distribution of the microbial load, but without integration on the lethality achieved during heat up and cool down of the CMTM.

2. Same as (3) with the exception that the CMTM impact limiter and parachute canister are exposed to a sterilization cycle prior to CMTM assembly and terminal sterilization. This pre-terminal cycle need only be for the time and temperature period necessary to sterilize the internal contamination of the impact limiter and parachute canister, plus the additional D values necessary to achieve the required probability of sterility. It has been estimated that the balsa wood impact limiter has an internal contamination of 2.6×10^5. Thus, any sterilization process encompassing a minimum of 6 D values will insure the internal sterility of the impact limiter. In a similar manner it would take a minimum sterilization cycle of 7 D values at the most heat-resistant point to insure

sterility of the interior material of the parachute canister (2.8×10^6 microorganisms), plus the additional D values to achieve the required probability of sterility if heat up and cool down lethality and distribution of the microbial load is not considered.

3. A dry heat terminal sterilization cycle for the CMTM which considers the effects of both distribution of the CMTM microbial load and the lethality achieved during heat up and cool down.

The CMTM biological load estimates were based upon literature surveys and best engineering judgement. No biological assays were conducted. If the final terminal sterilization cycle for the CMTM is to be calculated with consideration for the distribution of the microbial load but without integration of the lethality achieved during heat up and cool down, it becomes necessary to find that zone which requires the maximum process time to sterilize. For purposes of discussion we have chosen a D value of 3.5 hours at 125°C and a Z value of 25°C. Using these values and the microbial load estimates derived in Task 11b, a series of hypothetical calculations can be made. For instance, if the interior core of the balsa wood impact limiter does in fact turn out to be the most refractory zone then the terminal cycle would be based upon this zone. It has been estimated that the impact limiter core ($382\ in^3$) contains 2.1×10^3 microorganisms. Thus, the terminal sterilization cycle for the assembled CMTM would be equal to the time necessary to heat this zone to 125°C, plus 14.0 (4 x 3.50 hours to reduce microbial burden by 4 D's) plus the values D necessary to achieve the required probability

of sterility. This approach is probably most unacceptable of the three approaches discussed since the electronic components (and other exposed elements) would receive about 414 hours of 125°C heat. This estimate is based on a heat-up time of 200 hours for the impact limiter, a sterilization cycle of 14.0 hours, and a cool-down time of 200 hours[2].

If the approach of integrating the lethality during heat up and cool down is used, then the total process time is reduced significantly. This is primarily based upon the fact that all CMTM subassemblies are exposed to varying degrees of lethality during the period necessary to heat the most heat-resistant point of the CMTM to any terminal sterilization temperature. For example, if we again use the interior core of the balsa wood impact limiter as the most heat-resistant point in the capsule and assume the following constraints (inner core = 382 in^3 and population density of 2.1×10^3 microorganisms), it would take an estimated 200 hours to heat the innermost part of this sphere to 125°C. The calculation was made by JPL and assumes:

1. The surface of the impact limiter (glass cloth and resin) reaches 257°F instantaneously and remains at this temperature for the duration of the analysis.

2. The balsa wood thermal properties were taken as: density - 7.5 lbs/ft^3, thermal conductivity - 0.0275 BTU/hr-ft - °F; and C_p = 0.3 BTU/lb - °F.

3. The glue which holds the balsa wood blocks together has a negligible effect on the heat transfer properties.

4. The initial temperature of the block was +70°F.

However, it can be seen that after 120 hours (approx.) the innermost sphere has been exposed to sufficient D values to assure sterility and it remains necessary only to heat the total CMTM assembly for that further amount of time to insure sterility to the desired level (see Table 5-1).

By pre-sterilizing the interiors of the parachute canister and of the impact limiter it can be seen that the total process time can be further reduced. Again, using the burden estimates derived in Part 2, we can see that the total microbial load of the CMTM after assembly is substantially reduced if the interior microbial load of the impact limiter and parachute canister are reduced by a pre-terminal sterilization cycle.

Utilizing the forementioned approach, it can now be assumed that the CMTM zone requiring the maximum sterilization process time is not the impact limiter or parachute canister. It may, for discussion purposes, be an interior zone of one of the electronic bays. Arbitrarily, the interior (conformal coating) of the data encoder system has been selected as the zone now requiring the maximum sterilization process time. The total process time to sterilize this zone will be dependent upon the thermal characteristics of this particular zone and those of the heating medium. Similar calculations to those previously discussed can be used in deriving the appropriate terminal sterilization cycle. It has been estimated that this zone contains 6×10^3 microorganisms.

Assuming the terminal sterilization process has been suitably adapted to the heat transfer characteristics of the CMTM subassemblies, the internal and external sterility of the CMTM may be guaranteed to the

TIME, HOURS	TEMPERATURE - °F						
	OUTER RADIUS 22.5"	RADIUS 18.0"	RADIUS 13.5"	RADIUS 9.0"	RADIUS 4.5"	CENTER R = 0	
0	257	70	70	70	70	70	
10	257	152	102	80	72	71	
20	257	189	144	111	94	89	
30	257	211	174	144	126	120	
40	257	224	196	172	157	151	
50	257	233	213	194	182	178	
60	257	239	224	210	201	198	
70	257	244	233	226	215	213	
80	257	247	239	231	226	224	Approx 4.0"
90	257	250	244	238	234	233	
100	257	252	247	243	240	239	
110	257	253	249	246	244	244	
120	257	254	251	249	248	247	
130	257	255	253	251	250	250	
140	257	256	254	253	252	251	
150	257	256	254	254	253	253	
160	257	256	255	254	254	254	
170	257	256	255	255	255	254	
180	257	256	256	255	255	255	
190	257	257	256	256	255	255	
200	257	257	257	256	256	256	

TABLE 5-1

COMPUTED TEMPERATURES AS A FUNCTION OF TIME AT SIX RADIAL LOCATIONS IN THE IMPACT LIMITER

the required probability as set forth in the NASA planetary quantitative specifications.

III. CONCLUSIONS.

By utilizing the three-fold approach of (a) burden determination, (b) application of terminal heat sterilization and (c) monitoring and verifying the heating process, sterilization within NASA Planetary Quarantine guide lines could be obtained.

IV. RECOMMENDATIONS.

It is possible to verify sterilization of the CMTM by at least two different methods; one is a dynamic approach with recording thermocouples, and the second is a static approach with chemical reactions controlled by inherent catalysts in microorganisms.

It is recommended that both the dynamic and static methods be utilized.

V REFERENCES

1. Voyager Project Planetary Quarantine Plan, Third Revision, July 1967.

2. Campbell, A. Transient Analysis of Impact Limiter and Parachute Canister, Interoffice Memo 2941-587, August 7, 1967.

3. Stern, J. A. (1966) Preliminary Discussion of Method if Integrating Heat Up and Cool Down Times on the Spacecraft, Spacecraft Sterilization Advisory Committee Report.

APPENDIX 1

STUDY OF A CHEMICAL INDICATOR AS AN INDEX

OF

THERMAL MICROBIAL KILL

I. INTRODUCTION

The objective of this study was to examine enzyme systems which might be useful as chemical indicators for the thermal destruction of bacterial spores. The enzyme or enzymes (if proved satisfactory) might then accompany hardware during thermal sterilization and be used as additional means of verifying sterilization.

Enzymes are protein or catalysts which can alter biochemical reactions, as for example:

$$H_2O_2 \xrightarrow[(\text{Enzyme})]{\text{Catalase}} 2\,H_2O + O_2$$

The reaction (degradation of peroxide) in the presence of a specific amount of catalase will proceed at a specific velocity to produce a specific amount of H_2O and O_2 in a given environment. If the amount of active enzyme is reduced the velocity of the reaction will be reduced. Thus, by determining the product formed and the time of formation, an index of active enzyme present can be obtained.

Enzymes, as previously stated, are proteins which lose their catalytic activity when denatured. Since heat is a denaturing agent, it was decided to examine the thermal inactivation of an enzyme and thermal kill of bacterial spores to see if a relationship between enzyme inactivation and spore kill exists. It should be noted that a major portion of thermal microbial kill mechanism is involved with enzyme and cell protein denaturation.

II. EXPERIMENTAL PLAN

A. Three enzymes (in a dry, powdered state) were screened for their stability to dry heat at 125° C (acid phosphatase, alkaline phosphatase, and ribonuclease).

B. Of the three enzymes screened, alkaline phosphatase was found to be the most satisfactory for our experimental needs, and thus was chosen for further investigation.[2]

C. Thermal resistance studies of Bacillus globigii at 125° C for different periods of time were conducted in parallel with the enzyme inactivation study.

D. The alkaline phosphatase reaction utilized was as follows:

$$\text{p-nitrophenyl phosphate} \xrightarrow[\text{pH } 10.4]{\text{Alkaline Phosphatase}} \text{p-nitrophenol and phosphate}$$

1. The degree of enzyme inactivation was followed by the rate of formation of p-nitrophenol[2,3] using a Cary 14 recording spectrophotometer.

E. The enzyme inactivation curve was compared to that of the B. globigii thermal inactive curve.

III. MATERIALS AND METHODS

A. Preparation of Reagents for the Alkaline Phosphatase Reaction.

1. Alkaline Buffer

Dissolve 0.750 grams of glycine in approximately 75 ml. H_2O. Add 8.5 ml. of 1N NaOH and adjust the volume to 100 ml. with distilled H_2O. (Yields a pH of 10.4 when "read" with a pH meter.)

2. p-nitrophenol Standard Solution

Dissolve 0.0695 grams of p-nitrophenol in H_2O and adjust the volume to 100 ml. with distilled H_2O. (1 ml = 5μM)

3. p-nitrophenol Working Standard

Place 2 ml. of the standard solution in a 50 ml. volumetric flask and adjust to 50 ml. with distilled H_2O. (1 ml = 0.2μM)

4. 0.4% Disodium p-nitrophenyl Phosphate Solution.

Dissolve 0.4 grams of disodium p-nitrophenyl phosphate in 100 ml. of H_2O.

B. Dry Heat Inactivation Procedure for Alkaline Phosphatase

1. Five mg. samples of dry, powdered alkaline phosphatase (Sigma Bio-chemical Co.) were placed in 50 ml. covered beakers containing thermocouples (previously calibrated). The thermocouple was placed directly in the powdered alkaline phosphatase and temperatures "read".

2. The enzyme was heated to 125°C as indicated by the thermocouple readings.

3. Enzyme samples were heated for 1 hr., 4 hrs., 12 hrs., 16 hrs., 20 hrs., 24 hrs., 40 hrs., and 64 hrs.

4. The comeup time to reach 125° C was 30 minutes. The "come up time" reading was added to each of the time values.

C. Dry Heat Kill Procedure for Bacillus globigii Spores

1. The procedure used was that described in "Determination of the Heat Resistance of Microbial Isolates from the EASL, AVCO Document #AVSSD-0148-67-CR, Reorder #67-116 with the following exception. The heating time was extended to 1 hr., 4 hrs., 8 hrs., and 12 hrs.

D. Method of Assaying Enzymatic Activity

1. A standard curve of p-nitrophenol was prepared using the following reagents and volumes.

Working Standard of p-nitrophenol (ml)	H_2O (ml)	10% NaOH (ml)	μM^* p-nitrophenol (ml)
0.0	4.0	1.0	0.00
0.1	3.9	1.0	0.02
0.2	3.8	1.0	0.04
0.3	3.7	1.0	0.06
0.4	3.6	1.0	0.08
0.5	3.5	1.0	0.10
0.6	3.4	1.0	0.12
0.7	3.3	1.0	0.14
0.8	3.2	1.0	0.16

See Figure 5-1 for Standard Curve

* μM = micro moles

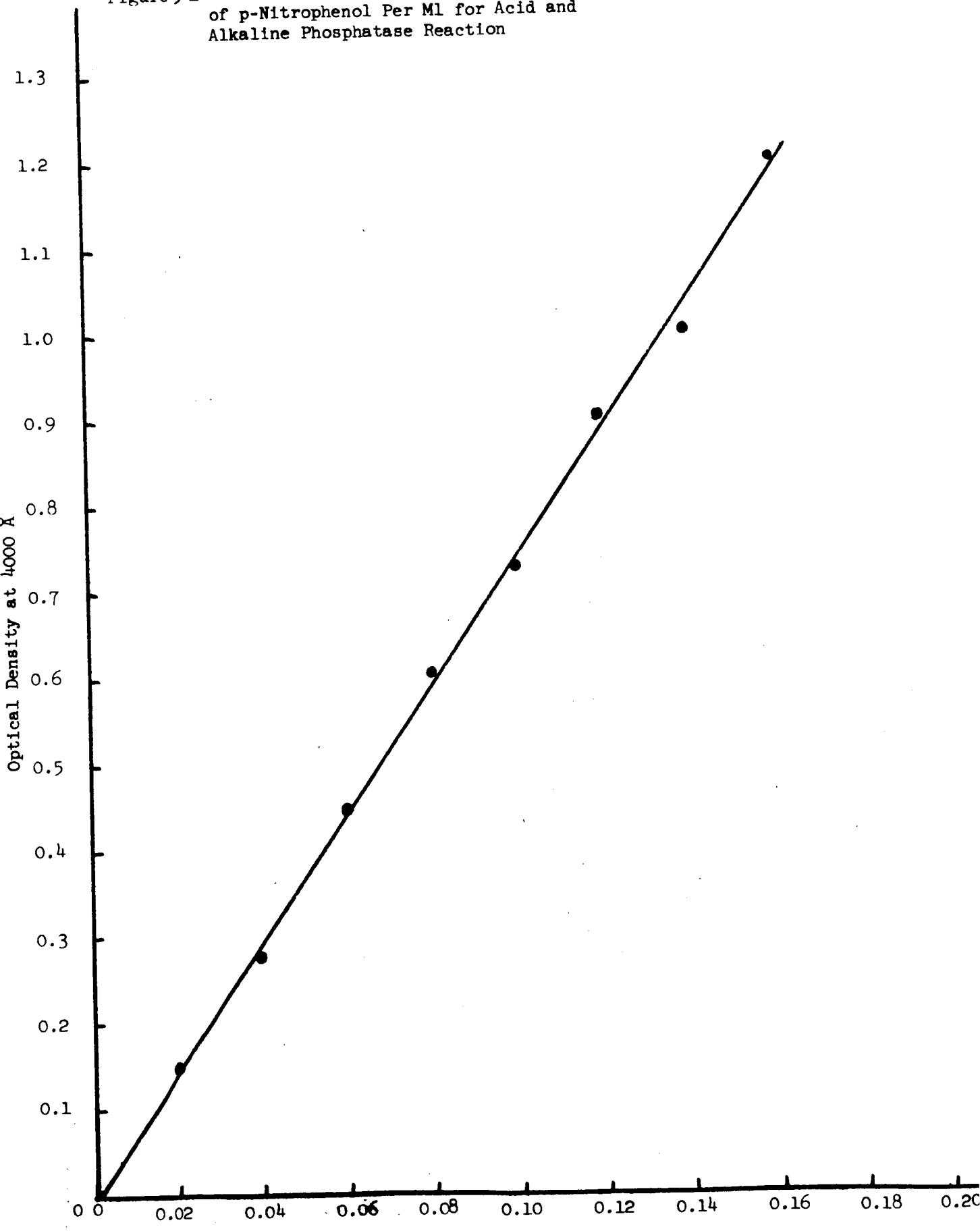
TABLE 5-2

Standard Calibration Curve For

p-Nitrophenol at 4000 Å

Optical Density	Path Length (cm)	H_2O (ml)	p-Nitrophenol Working Std. (ml.)	10% NaOH	μM p-Nitrophenol (ml.)
0.000	1.0	4.0	0.0	1.0	0.00
0.150	1.0	3.9	0.1	1.0	0.02
0.280	1.0	3.8	0.2	1.0	0.04
0.450	1.0	3.7	0.3	1.0	0.06
0.610	1.0	3.6	0.4	1.0	0.08
0.725	1.0	3.5	0.5	1.0	0.10
0.910	1.0	3.4	0.6	1.0	0.12
1.066	1.0	3.3	0.7	1.0	0.14
1.202	1.0	3.2	0.8	1.0	0.16

Figure 5-1 Standard Curve- Moles Concentration of p-Nitrophenol Per Ml for Acid and Alkaline Phosphatase Reaction



2. Assay Reaction Required to Evaluate Enzymatic Activity

a.) Add 1.5 ml. of alkaline buffer to a test tube.

b.) Add 1.0 ml. of distilled water to "a".

c.) Dissolve weighed powder form of alkaline phosphate (heat treated) to 1.5 ml. of substrate (p-nitrophenol phosphate) and allow reaction to proceed for 5 minutes.

d.) Add 1.0 ml. of 10% NaOH to stop the reaction, elevate the pH and produce the yellow color of p-nitrophenol.

e.) Determine the resultant optical density of the p-nitrophenol at the alkaline pH in a spectrophotometer (Cary 14 was used) at 4000 Å . See Table 5-2 and Figure 5-1 for the values and Standard Curve for p-nitrophenol.

f.) Compare optical densities of product produced from heat treated with Standard Curve to obtain μM/ml of p-nitrophenol.

g.) Prepare plot of enzyme activity (μM/ml p-nitrophenol obtained) versus time enzyme heated at 125° C.

h.) Extend experiment until infinite inactivation of enzyme is established. (This is point where continued time at the given temperature does not cause further reduction of the enzyme activity.)

IV. RESULTS

1. Of the three enzymes examined, alkaline phosphatase, acid phosphatase and ribonuclease, alkaline phosphatase was selected for

the model enzyme reaction.

2. Table 5-3 lists the units of alkaline phosphatase activity obtained after heating the enzyme from 0 to 64 hrs. at 125° C.
3. Figure 5-2 is a plot of the values obtained from Table 5-3
4. Figure 5-3 is the curve obtained when Bacillus globigii spores were heated from 0 to 60 minutes at 125° C.

V. DISCUSSION

The enzyme alkaline phosphatase has a significant degree of thermal stability which makes it a candidate as a chemical indicator of dry heat sterilization.

When comparing the curves of B. globigii spore heat inactivation and alkaline phosphatase inactivation it can be seen that there is a direct reduction of spore viability and enzyme activity as the heating process progresses. Thus, it might be possible from a microbiological monitoring standpoint, to use packaged quantities of enzyme to accompany the hardware as it goes through the dry heat sterilization cycle.

The amount of enzyme in the spore must be correlated with the amount of dry enzyme powder to establish a correlation of thermal spore kill to enzyme heat denaturation in the dry powdered state. To be a useful indicator, the dry powdered enzyme must be thermally inactivated at a slower rate than the spore to which it is being correlated.

As can be seen from Figure 5-2, the alkaline phosphatase reaches its infinite denaturation value between 4 and 12 hrs. of exposure to dry heat at 125° C. This factor would limit the value of the enzyme as a chemical indicator of dry heat sterilization. The degradation rate of the enzyme activity might be adjusted by the use of an inert carrier added to the powered enzyme.

TABLE 5-3

Alkaline Phosphatase Activity Determined at 4000 Å After Exposure to 125° C for Varying Lengths of Time

Time in Hours of Exposure at 125° C	Optical Density	Path Length (cm)	Factor	Graph Value	μM/ml of Product
0	0.725	0.005	200	0.099	19.6
1	0.500	0.005	200	0.063	12.6
4	0.165	0.005	200	0.021	4.2
12	0.130	0.050	20	0.017	0.34
16	0.220	0.100	10	0.030	0.3
20	0.230	0.100	10	0.031	0.3
40	0.245	0.100	10	0.033	0.3
64	0.220	0.100	10	0.030	0.3

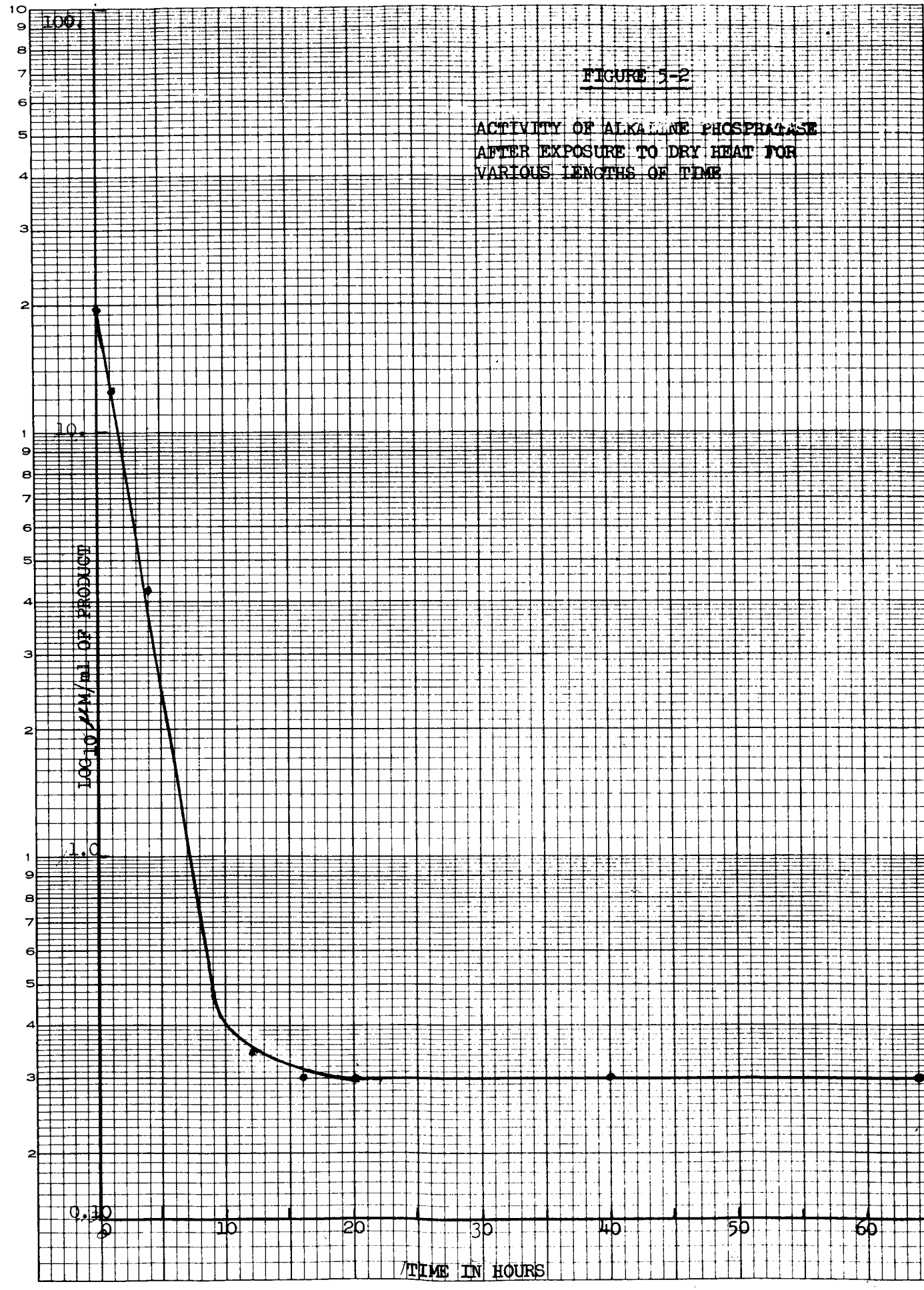
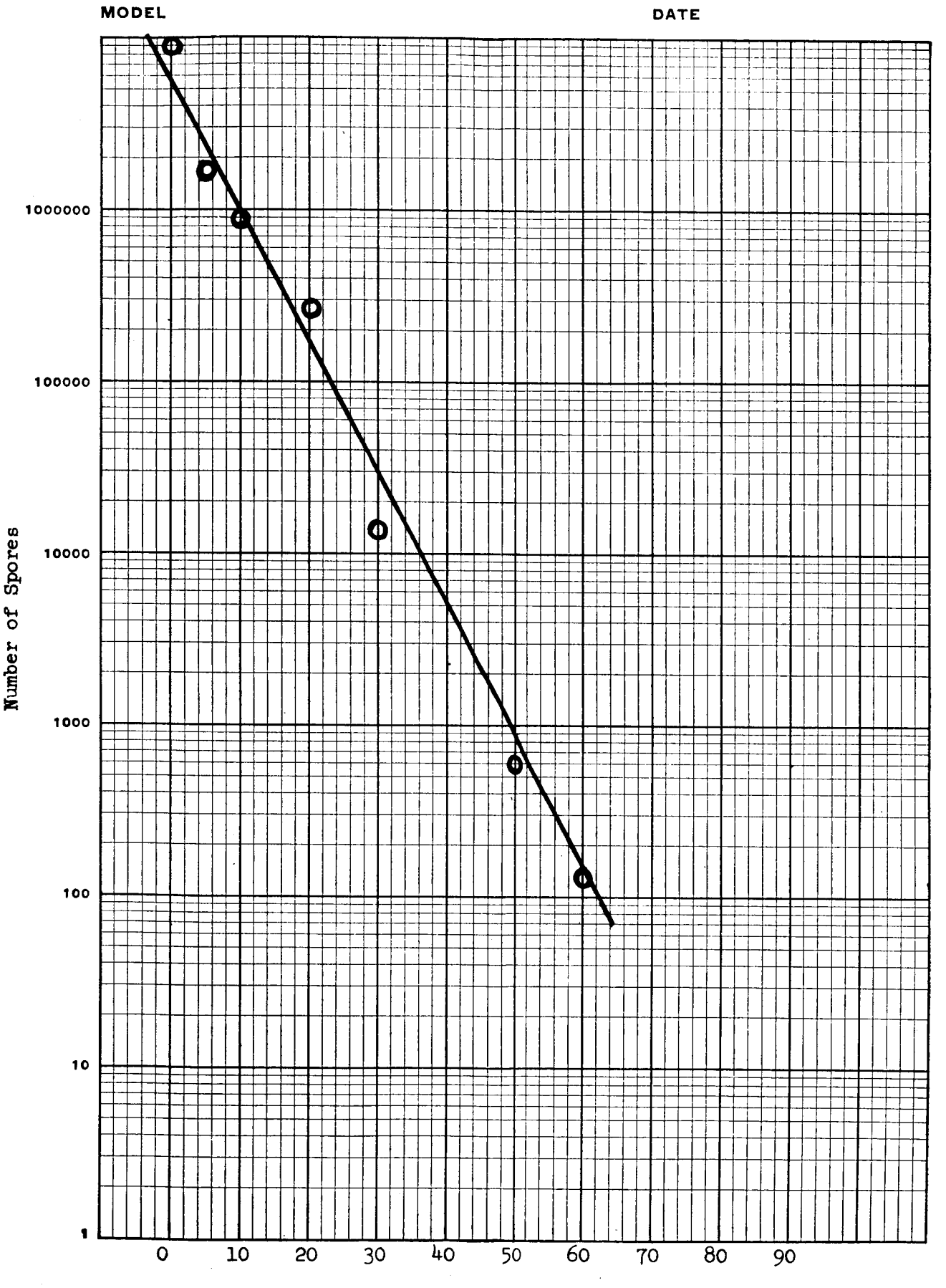


FIGURE 5-2

ACTIVITY OF ALKALINE PHOSPHATASE AFTER EXPOSURE TO DRY HEAT FOR VARIOUS LENGTHS OF TIME

Figure 5-3 Heat Resistance of B. globigii



Heat Resistance: Bacillus globigii

A carrier which would be chemically inert, thermo-stabile, and water insoluble would be ideal. Compounds such as talc, titanium dioxide, silicon dioxide, or aluminum oxide in a dry, finely powdered state would meet these requirements. The addition of a carrier may possibly act as a protective material and thus slow the denaturing effects of the heat. By varying the ratio of enzyme to carrier, it might be possible to obtain a preparation which would reach its infinite denaturation value after 16, 18, 20 or more hours exposure to dry heat. The value of such a preparation, or series of preparations as a dry heat sterilization indicator is obvious.

The problem of removing the carrier from the enzyme could be handled quite easily by either filtration or centrifugation. Since the enzyme is water soluble and the carrier insoluble, all one would have to do would be to suspend the preparation in alkaline aqueous buffer and then filter or centrifuge to remove the carrier. The clear filtrate would then be available for the colormetric assay of enzyme activity.

VI. CONCLUSIONS

1. The enzyme alkaline phosphatase shows promise for use as a chemical dry heat sterilization indicator.

VII. RECOMMENDATIONS

1. Continue experimentation using alkaline phosphatase as a possible indicator of dry heat sterilization.

   a.) Investigate the different types of carriers that might be used with the enzyme to increase the time needed for enzyme infinite inactivation at 125° C.

   b.) Investigate the different ratios of enzyme to carrier so as to obtain a tightly controlled system.

VIII. REFERENCES

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3. Koningsberger, V. V., and Bosch, L., "Regulation of Nucleic Acid and Protein Biosynthesis", Volume 10, Elsevier Publishing Co., 1967.

4. Sussman, A. S., and Halvorson, H. O., "Spores, Their Dormancy and Germination", Harper and Row Publishing House, New York, New York, 1966.

I. INTRODUCTION

The main effort in this task was to investigate and identify techniques which would guarantee the integrity of the sterilization canister in which the sterilized CMTM was sealed.

Procedures which might be used to detect leaks, holes, or cracks in the canister would be investigated.

II. APPROACHES CONSIDERED

A major constraint of this study was the fact that the sterilization canister was designed with a breathing system[1] having a HEPA filter at its outlet for out-gassing and pressure relief. This design mode precluded the adoption of methods that might be otherwise used on flight hardware. (The canister has a known leak rate.) Thus, the solutions to the problem would require a system or device which would allow for the breathing process.

A. Present Possible Approaches to the Problem

Three approaches were considered. They include:

1. Use of Constant Pressurization with Sterile Dry Nitrogen

   a. The sterilized canister (containing the sterile CMTM) is connected to a sterile Nitrogen source with an in-line pressure gauged system. Nitrogen is then "bled" into the canister through a HEPA by means of a her-

metically sealed sterile line at a rate as to insure that there is no backflow.

b. When ambient temperature has been attained, a cap is placed tightly over the outside housing for the HEPA filter.* The cap will reduce the leak rate of the HEPA filter outlet, thus reducing the known leak rate significantly.

c. The canister is then pressured with sterile nitrogen to the maximum level obtainable (0.5 psi minimum).

d. The leak rate for the canister and the HEPA filters, as previously mentioned, will be determined and the amount of nitrogen necessary to maintain a given positive pressure differential per unit time estabilished.

e. By using a cap to seal off the HEPA filter and the addition of sterile dry nitrogen, a reduction in the leak rate or loss of nitrogen pressure can be maintained and monitored with adequate sensitivity.

f. The loss of pressure can be monitored by means of pressure gauges. If an abnormal drop in pressure id observed, it can be inferred that a hole, or a cracking of the canister has occurred. However, as long as a certain minimum positive pressure, yet to be determined, is maintained in the canister, the CMIM will remain sterile.

* On the "Breathing System"

PART 6

DEVELOPMENT AND EVALUATION OF

PROCEDURES NECESSARY TO MONITOR THE STERILIZED CMTM

g. This approach is the one recommended for the present solution to the sterility monitoring problem.

2. Use of a Cover Plate and Valving System to Close off the Breathing System.

a. This approach would require the design of an adapter and valving system which could be welded over the breathing system of the canister.

b. The canister would be placed in the terminal sterilization oven and heated. The hot gases would then leave the canister via the breathing system and valve system.

c. The valve would be closed when the canister reached ambient temperature and pressure, either manually or by servo mechanism.

d. The atmosphere of the canister could have helium added which could be monitored for leaks with a leak detector.

e. This system was considered unacceptable for the following reasons:

1.) The questionable reliability of the valve system in preventing leakage and possible microbial contamination.

3. Double Bagging of the Canister

a. The sterilization canister would be placed inside of

two bags. The inner bag (next to the canister) would have a degree of stretch and the outer bag would fit loosely over the inner bag. The bagged canister would then be placed in the Terminal Sterilization Oven and heated. As the gas in the CMTM expands and leaves the canister via the breathing system, the inner bag would inflate and press tightly against the outer bag. As the CMTM and canister cooled, the gas would contract and the inflatable inner bag would collapse.

The system could be monitored with a leak detector for helium.

(Note: Helium could be added to the atmosphere of the canister and/or CMTM.)

b. The outer bag could be a laminate of mylar, aluminum and polyethylene films. The inner bag might be made of a synthetic rubber as chloroprene or some related compound.

c. This approach was considered unsatisfactory for the following reasons:

1.) Possibility of tears or holes in the bagging material.

2.) Problems of sealing the bags to be air-tight and humidity-proof.

3.) Effects of 125°C on the bagging materials.

4.) Problems of removing the bags for post-sterilization handling.

B. Future Possible Approach to the Problem of Sterility Monitoring

The most direct approach to meet the objective of this study would require the redesign and the fabrication of new sterilization canister. (The redesign and fabrication of a new CMTM was not feasible in Phase II.)

A new sterilization canister could be so designed that it might be hermetically sealed, or welded shut. The canister, in-addition, might have a pressure relief system that could relieve the pressure buildup due to the terminal sterilization process. The addition of a gas (to the canister) such as an inert gas, or mercaptan could then be used to monitor leaks or holes. The presence of leaks or holes could then serve as an indication of possible microbial contamination. The inert gas could be detected by the use of a leak-detecting device. If a mercaptan were used, its presence could be detected by the use of gas chromatography or by "sniffing". The average person can detect the presence of mercaptans by smell in approximately 10-20 parts per million level.

III. RECOMMENDATIONS

1. For the future, it is suggested that a redesign of the sterilization canister be undertaken to implement the hermetically sealed concept of sterilization monitoring.

IV. REFERENCES

1. Sterilization Canister blue print, Number OJ-1035, FANSTEEL/TORANCE INC., 11/30/66.

PART 7

PROPOSED MICROBIOLOGICAL ORGANIZATION FOR

CMTM ASSEMBLY OPERATIONS

I. INTRODUCTION

In response to the task statement requirement, a microbiological organizational structure necessary to implement and operate the microbiological monitoring and assay of the CMTM is proposed.

This organizational plan includes the interrelationship between the Microbiological, Quality Assurance, Assembly and Facility personnel. In addition, the responsibilities and authority of each group is delineated.

II. PHILOSOPHY OF APPROACH

In developing a rationale to define the relative roles of the four technical groups in the sterilization assembly of a capsule, the following approach was employed.

In the case of non-sterile spacecraft assembly and test operations, the responsibility for on-time completion of the capsule assembly rests with an operations manager and his supporting staff. The disciplines of assembly, test, facility operations, and quality assurance in turn, and time phasing, play roles of prime responsibility for performance to the operations manager. To wit, the Assembly Group is responsible for the successive assemblies of sub-assemblies, a test, or system test group, as required, performs the necessary sub-system and system tests at defined points in the assembly sequence.

The Facilities Group supports all groups, providing utility, handling and shelter readiness functions throughout the assembly process. Furthermore, the Quality Assurance Group performs an overall monitoring function throughout the process, to verify that all requirements have been met.

No mention has been made of the function of the Design Engineering Group in the above, although, at this time in a development program, the role of design engineering is primarily, or should be, that of support to the project office in the resolution of problems or discrepancies that are attributed to design deficiencies. It is assumed that at the time assembly of a flight vehicle is initiated, that (a) the "design" has been completely defined by appropriate specifications and drawings, and (b) a proof test model, or models, of the vehicle has been fabricated to preliminary specifications and drawings, tested, evaluated, and "design freeze" accomplished.

The present consideration of planetary quarantine and resulting requirements for decontaminated, if not sterile, assembly operations introduces many new operating restraints and controls on the assembly, facility, test, and quality assurance disciplines. An entirely new set of plans and procedures which factor in these new constraints must be generated. Obviously, then, it follows, that an "Assembly and Test Plan" must result, which integrates the microbiological control operation into the conventional Assembly and Test Plan dealing with mechanical assembly and test procedures only.

The integrated Assembly and Test Plan, in format, would resemble the present "CMTM Assembly and Disassembly Plan" but, in addition, would incorporate appropriate microbiological operations related to monitoring and assay, including the quality assurance surveillance of these operations and, additionally, the Facilities Group support. Such a plan for CMTM assembly purposes would be implemented under the detailed supervision, or direction, of the Assembly Group.

The responsibility for the integration of the microbiological control operation into the Assembly and Test Plan rests with the Microbiological Group. The ultimate responsibility for on-time completion of all operations connected with the CMTM Assembly and Test Plan rests with the Project Manager; however, once the Assembly and Test Plan is developed, approved, and released, the Assembly Group Manager will be designated as responsible to the Project Manager for scheduling, detail planning, and supervision of day-to-day operations in accordance with the Plan. Deviations from the Plan will not be permitted without the approval of the Project Manager.

III. MICROBIOLOGICAL ORGANIZATION

The Microbiological Organization or Group is an integral part of the AVCO operation at J.P.L. as shown in Figure 7-1. Figure 7-2 graphically demonstrates the relationships between the Assembly Group, the Microbiology Group, the Quality Assurance Group, and the Facilities Group for the CMTM Assembly Program. Figure 7-3 presents the structure

of the Microbiology Group for the performance of the microbiological aspects of the CMTM Assembly Program.

IV. RESPONSIBILITIES AND AUTHORITY OF THE DISCIPLINES FOR THE CMTM ASSEMBLY PROGRAM

A. Microbiology

1. Plan and execute the biological assay program for the CMTM Assembly Program.

2. Monitor and support the activities of the Assembly Group and Facilities Group which have a microbiological impact on the CMTM Assembly Program.

3. Establish and operate the microbiology laboratory.

4. Supply bioassayers for sample taking and monitoring.

   a.) Bioassayers to remove samples and prepare them for culture (place in sterile containers, etc.).

   b.) Bioassayers to take samples of CMTM and SADL Facility.

5. Observe the CMTM assembly process for biological impact. Report observations to the task supervisor.

6. Assay SADL Facility, biocoupons, tools, equipment, supplies and personnel for biological burden.

   a.) Culture samples for burden

   b.) Count colonies

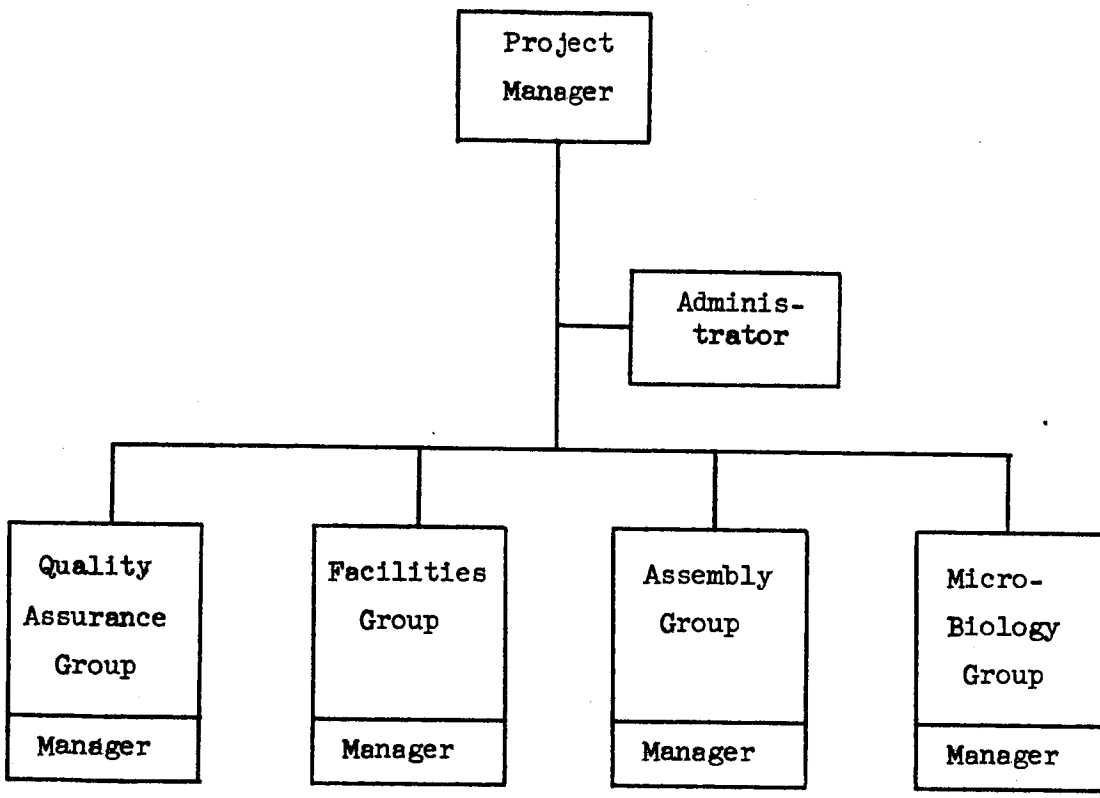

Figure 7-1 - Organization Chart for the AVCO Operation at J.P.L.

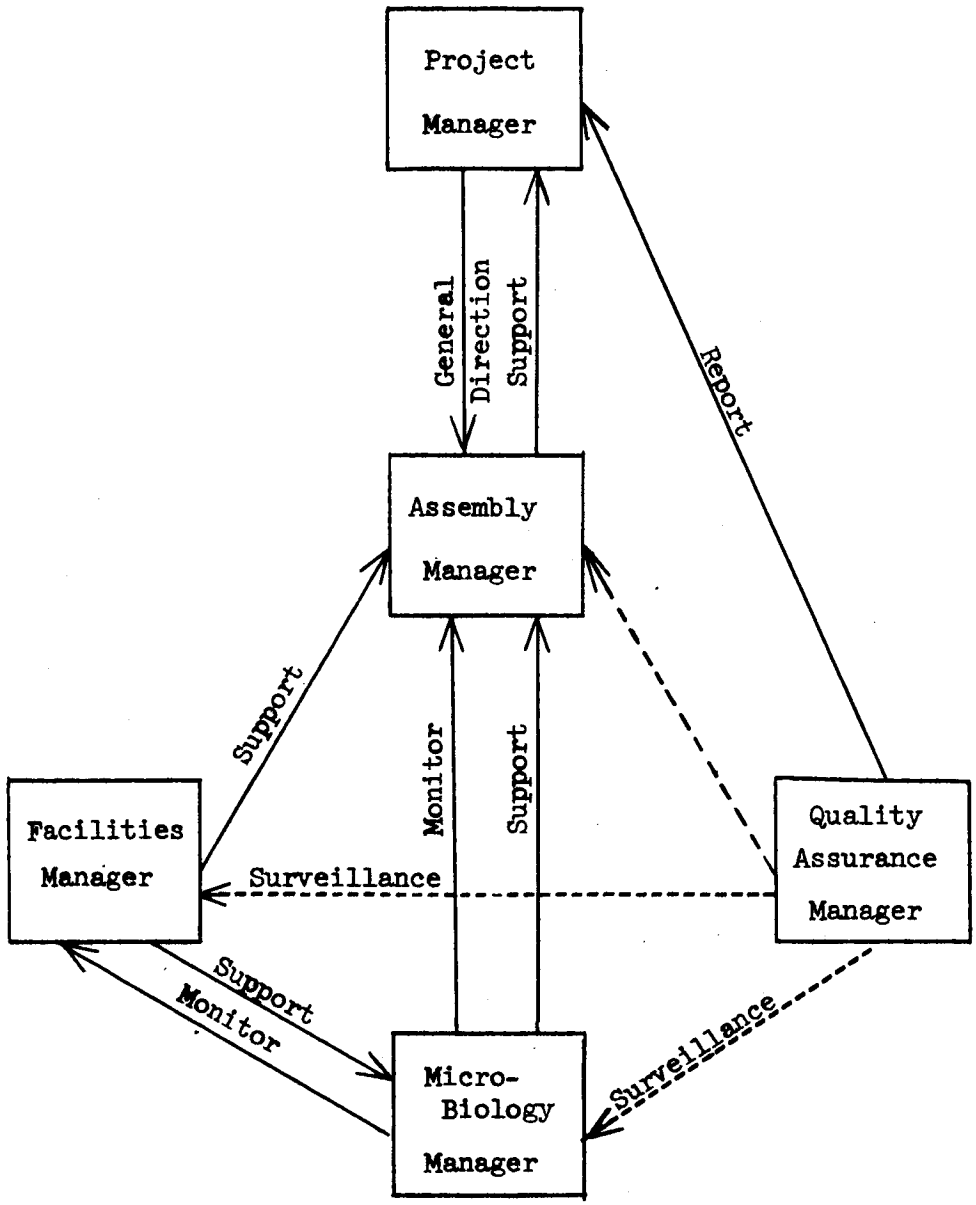

Figure 7-2 - Organization Chart Showing the Interrelationships Between Microbiology, Facilities, Quality Assurance and Assembly

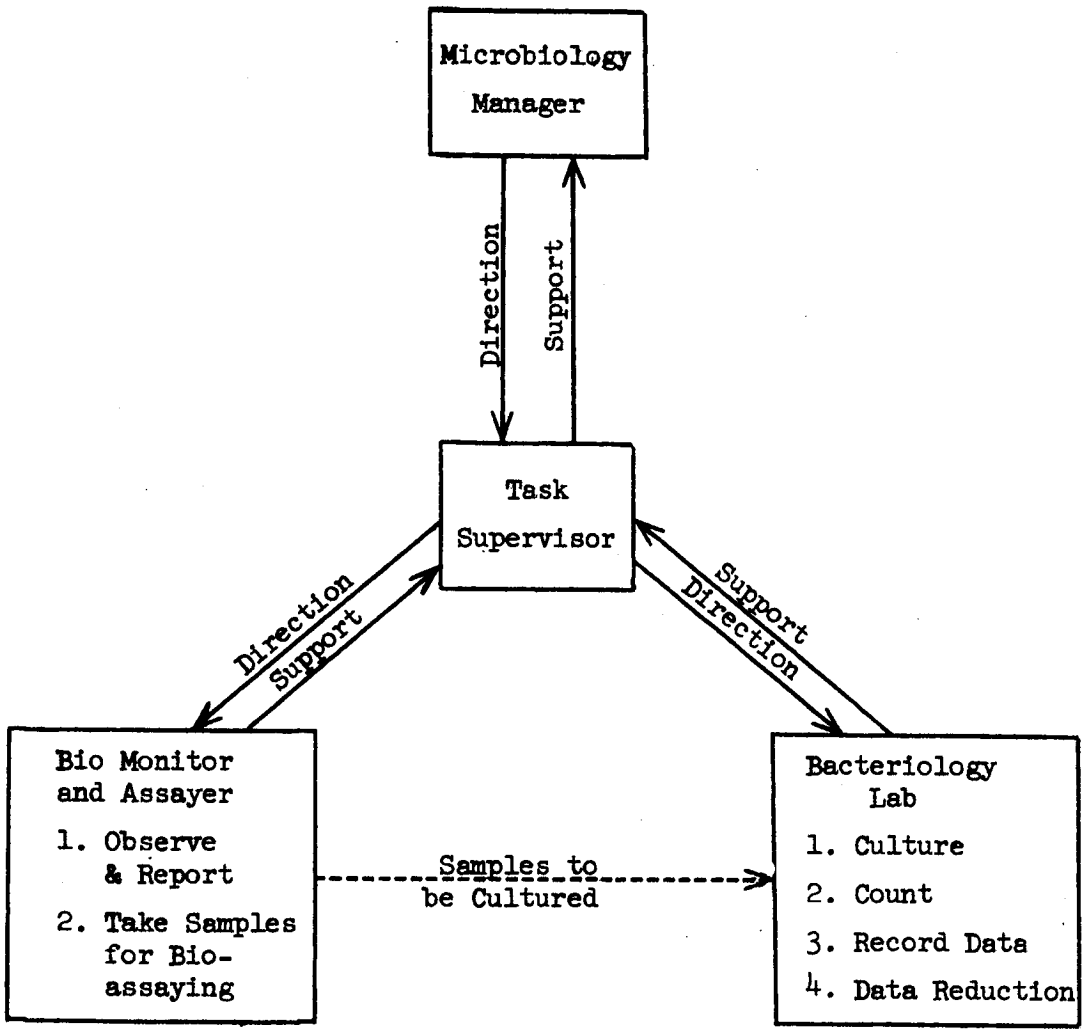

Figure 7-3 - Microbiology Group Organizational Chart for the CMTM Assembly Program

c.) Record data

d.) Reduce data

e.) Evaluate data

7. Run biological control systems.

8. Prepare reports on the results of the bioassay and general observations.

9. The Bio-group manager will be a member of the CRB, the Contamination Review Board.

B. Facilities

1. Operate the SADL Facility.

2. Facility support when and where needed for the CMTM Assembly Program.

3. Operate the ETO Decontamination Chamber

4. Operate the Terminal Heat Sterilization Chamber.

5. Decontaminate the necessary tools, equipment and supplies for the CMTM Assembly Program.

6. Maintain all equipment items in the Bio-laboratory.

7. Supply "trouble shooting" for the facility and facility items.

8. Monitor physical paramaters of the SADL Facility and Bio-laboratory areas.

9. The Facilities manager shall be a member of the CRB.

C. Assembly

1. Prepare the Assembly and Test Plan.

2. Schedule the CMTM assembly.

3. Perform the CMTM assemblies, disassemblies, cleaning, etc., per the Plan.

4. Supervise all activity in connection with the CMTM assembly.

5. The manager of the Assembly Group is a member of the CRB.

D. Quality Assurance

1. Quality Assurance shall monitor all incoming supplies, parts, equipment and devices as specified in the QA plan. (SADL Quality Assurance Program Plan, AVCO Document #AVSSD-0129-67-CR.)

2. QA shall monitor the CMTM assembly process for mechanical, assembly and biological requirements as specified in the QA plan.

3. QA shall monitor the measurement of SADL facility, physical and biological parameters as specified in the QA plan.

4. QA shall monitor the biological assay procedures as specified in the QA plan.

5. QA shall monitor and sign off on the certification of the SADL Facility.

6. QA shall log all observations and findings.

7. QA shall report their observations to the program manager and the managers of the various groups (Microbiology, Facilities, and Assembly).

8. QA shall report deviations or violations of procedures to the project manager, and manager or managers of the groups associated with or responsible for the deviations and institute a CRB (Contamination Review Board) meeting or a MRB (Material Review Board) meeting as required per the QA plan.

9. The QA manager shall be the chairman of the CRB and the MRB.

   a.) Contamination Review Board and Material Review Board. The members of the Contamination Review Board and the Materials Review Board shall be the managers of the Facility Group, Assembly Group, Microbiology Group, Quality Assurance Group, the Project Manager, and a

JPL representative and/or representatives as deemed necessary. As previously stated, the manager of the Quality Assurance Group shall be the chairman of the CRB and the MRB. The authority and the jurisdiction of both of these boards are cited in the SADL Quality Assurance Program Plan, AVCO Document #AVSSD-0129-67-CR, Reorder #67-103.

b.) The CRB and the MRB are the means for acting upon and correcting contamination and material problems which might arise during the CMTM Assembly Program.

E. Project Manager

1. The Project Manager has overall responsibility and authority for the CMTM Assembly Program.

2. The Project Manager delegates his authority to the manager of Assembly for the direction and supervision of the CMTM Assembly Program matters as he deems necessary.

3. The project manager will attend and chair weekly progress and information meetings concerning the CMTM Assembly Program.

a.) Those participating in the meeting will be the managers of Facilities, Microbiology, Assemblies, Quality Assurance and others as required.